

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Johnson, et al.
Appl. No.: 10/705,481
Conf. No.: 5154
Filed: November 10, 2003
Title: ORAL PRODUCTS CONTAINING NOVEL FLAVOR COMPOSITION
Art Unit: 1612
Examiner: Lezah Roberts
Docket No.: 3712038-00306

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on September 3, 2010. This Appeal is taken from the Final Rejection dated March 5, 2010 and the Advisory Action dated August 11, 2010.

I. REAL PARTY IN INTEREST

The real parties in interest for the above-identified patent application on Appeal are Wm. Wrigley Jr. Company by virtue of an Assignment dated March 8, 2004 and recorded at reel 015158, frame 0072 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are pending in the above-identified patent application. Claims 21 and 24-26 were previously withdrawn from consideration, and Claims 2, 3, 5, 6, 12, 13 and 15-17 were previously canceled without prejudice or disclaimer. Claims 1, 4, 7-11, 14, 18-20 and 27-33 stand rejected. Therefore, Claims 1, 4, 7-11, 14, 18-20 and 27-33 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A non-final Office Action was mailed on August 5, 2009, in which the Examiner rejected Claims 1, 4, 7-11, 14, 18-20 and 27-33 under 35 U.S.C. §112, first and second paragraphs, and Claims 1, 4, 7-11, 14, 18-20 and 27-33 under 35 U.S.C. §103. Appellants filed a Response to the non-final Office Action on November 3, 2009, in which Appellants amended the specification and Claims and argued against the written description, indefinite and obviousness rejections. A final Office Action was mailed on March 5, 2010, in which the Examiner maintained the rejections of Claims 1, 4, 7-11, 14, 18-20 and 27-33 under 35 U.S.C. §112, first paragraph and under 35 U.S.C. §103. Appellants filed a Response to the final Office Action on July 6, 2010, in which Appellants argued against the written description and obviousness rejections. An Advisory Action was sent by the Examiner on August 11, 2010, in which the Examiner entered the amendments, withdrew the written description rejection, and maintained the obviousness rejection. Appellants filed a Notice of Appeal on September 3, 2010. Copies of the non-final Office Action, final Office Action, and Advisory Action are included in the Evidence Appendix as Exhibits A, B and C, respectively.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 recites a consumable oral product (Abstract, lines 2-5; page 1, lines 14-21) comprising Erospicata oil (page 1, lines 14-21; page 2, lines 15-25), an effective amount of menthol (page 4, lines 1-2; Tables 2 and 6), a cooling agent (page 1, lines 14-21; Tables 1-9) and a heating agent (page 1, lines 23-29; Tables 2 and 6), wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total consumable oral product (page 3, lines 14-19; Tables 1-2 and 6), and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof (page 3, lines 3-13).

Independent Claim 11 recites a chewing gum product (Abstract, lines 2-5; page 1, lines 14-21; Tables 1-2) comprising Erospicata oil (page 1, lines 14-21; page 2, lines 15-25), an effective amount of menthol (page 4, lines 1-2; Tables 2 and 6), a cooling agent (page 1, lines 14-21; Tables 1-9) and a heating agent (page 1, lines 23-29; Tables 2 and 6), wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product (page 3, lines 14-19; Tables 1-2 and 6), and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof (page 3, lines 3-13).

Independent Claim 27 recites a method of enhancing a flavor in an oral consumable product (page 1, lines 14-21; page 14, line 9-page 15, line 11) comprising the steps of adding to a consumable oral product Erospicata oil (page 1, lines 14-21), an effective amount of menthol (page 4, lines 1-2; Tables 2 and 6), a heating agent (page 1, lines 23-29; Tables 2 and 6) and a cooling agent (page 1, lines 14-21; Tables 1-9), wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total oral consumable product (page 3, lines 14-19; Tables 1-2 and 6), and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon

oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof (page 3, lines 3-13).

Independent Claim 32 recites a method of producing a chewing gum product (Abstract, lines 2-5; page 1, lines 14-21; Tables 1-2) comprising the steps of adding to a composition that includes a gum base (page 4, lines 6-11; page 4, line 24-page 6, line 22), Erospicata oil (page 1, lines 14-21), an effective amount of menthol (page 4, lines 1-2; Tables 2 and 6), a cooling agent (page 1, lines 14-21; Tables 1-9) and a heating agent (page 1, lines 23-29; Tables 2 and 6), wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product (page 3, lines 14-19; Tables 1-2 and 6), and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof (page 3, lines 3-13).

Independent Claim 33 recites a method of reducing the amount of peppermint flavor required to achieve an organoleptic effect in a product (Abstract; page 1, lines 22-29; page 2, lines 15-25) comprising the steps of manufacturing the product with Erospicata oil (page 1, lines 14-21), an effective amount of menthol (page 4, lines 1-2; Tables 2 and 6), a cooling agent (page 1, lines 14-21; Tables 1-9) and a heating agent (page 1, lines 23-29; Tables 2 and 6), wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product (page 3, lines 14-19; Tables 1-2 and 6), and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof (page 3, lines 3-13).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a

mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,009,893 to Cherukuri et al. ("*Cherukuri*") in view of U.S. Patent No. 4,980,169 to Oppenheimer et al. ("*Oppenheimer*") and U.S. Plant No. 8,645 to Sturtz ("*Sturtz*"). Copies of *Cherukuri*, *Oppenheimer*, and *Sturtz* are included in the Evidence Appendix as Exhibits D, E and F, respectively.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged

from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

B. THE CLAIMED INVENTION

Independent Claim 1 recites, in part, a consumable oral product comprising Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent. The Erospicata oil comprises about 0.01% to about 5% by weight of the total consumable oral product. The heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

Independent Claim 11 is directed to a chewing gum product comprising Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent. The Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product. The heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

Independent Claim 27 recites, in part, a method of enhancing a flavor in an oral consumable product comprising the steps of adding to a consumable oral product Erospicata oil, an effective amount of menthol, a heating agent and a cooling agent. The Erospicata oil comprises about 0.01% to about 5% by weight of the total oral consumable product. The heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

Independent Claim 32 is directed to a method of producing a chewing gum product comprising the steps of adding to a composition that includes a gum base, Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent. The Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product. The heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol,

cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

Independent Claim 33 recites, in part, a method of reducing the amount of peppermint flavor required to achieve an organoleptic effect in a product comprising the steps of manufacturing the product with Erospicata oil, an effective amount of menthol, a cooling agent and a heating agent. The Erospicata oil comprises about 0.01% to about 5% by weight of the total product. The heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

C. THE REJECTION OF CLAIMS 1, 4, 7-11, 14, 18-20 AND 27-33 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully submit that the obviousness rejection of Claims 1, 4, 7-11, 14, 18-20 and 27-33 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the final Office Action, the Examiner asserts that the combination of *Cherukuri*, *Oppenheimer* and *Sturtz* renders the claimed subject matter obvious. See, final Office Action, pages 4-7. However, the Examiner has failed to establish a *prima facie* case of obviousness because the cited references fail to disclose each and every element of the present claims. Further, there exists no reason why the skilled artisan would have combined *Cherukuri*, *Oppenheimer* and *Sturtz* to arrive at the presently claimed subject matter.

1. The Presently Claimed Oral Products and Advantages Provided by Same

Independent Claims 1 and 11 recite, in part, products comprising Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Similarly, independent Claims 27 and 32 recite, in part, methods comprising the steps of adding to a product Erospicata oil, menthol, a heating agent and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product. Independent Claim 33 recites, in part, methods of reducing the amount of

peppermint flavor required to achieve an organoleptic effect in a product comprising the steps of manufacturing the product with Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product.

The present claims provide products including Erospicata oil, a non-menthol cooling agent and menthol. See, specification, page 1, paragraph 4; paragraph 12, lines 1-4; page 2, paragraph 19. The unique combination of Erospicata oil and a non-menthol cooling agent provides a novel flavor which reduces the cost of peppermint-flavored products. See, specification, page 1, line 14-page 2, line 13; page 4, lines 1-2. Menthol may also be included in the product as an additional flavoring agent to kill germs. See, specification, page 4, lines 1-2. Furthermore, by including the Erospicata oil in an amount between 0.01% and 5% by weight of the product, the product provides a unique flavoring benefit. See, specification, page 4, lines 12-23; page 11, lines 2-16; Tables 1-2 and 6. Appellants respectfully submit that the cited references are deficient with respect to the present claims.

2. The Cited References Fail to Disclose or Suggest Each and Every Element of the Present Claims

Appellants respectfully submit that the cited references are deficient with respect to the present claims because they fail to disclose or suggest every element of the present claims and, thus, fail to render the claimed subject matter obvious. For example, *Cherukuri*, *Oppenheimer*, and *Sturtz* fail to disclose or suggest a consumable oral product comprising Erospicata oil, in an amount of about 0.01% to about 5% by weight as required, in part, by all of independent Claims 1, 11, 27 and 32-33 and Claims 4, 7-10, 14, 18-20 and 28-31 that depend therefrom. In fact, neither *Sturtz*, *Cherukuri* or *Oppenheimer* disclose any amounts of Erospicata oil in any confectionery product at any place in the disclosures, let alone the presently claimed amounts of Erospicata oil.

Instead, *Sturtz* is entirely directed to a low-menthol Erospicata plant and fails to mention the use of Erospicata in any confectionery product whatsoever, let alone the presently claimed amounts of Erospicata oil. See, *Sturtz*, Title; Abstract, lines 1-4; Column 1, lines 19-26. *Cherukuri* is entirely directed to an oral composition comprising menthol and N-substituted-p-menthane carboxamide and fails to even mention Erospicata oil. See, *Cherukuri*, page 1, column

2, lines 34-38. *Oppenheimer* is entirely directed to an oral composition containing a volatile oil such as menthol in combination with a sensorially undetectable amount of a volatile oil modifying agent. However, *Oppenheimer* also fails to disclose or suggest Erospicata oil. See, *Oppenheimer*, page 2, column 2, lines 5-12. Indeed, the Examiner has failed to cite to any portion of *Cherukuri*, *Oppenheimer* or *Sturtz* that discloses the presently claimed amounts of Erospicata oil, and fails to rebut Appellants' argument that the cited references fail to disclose same at any place in the Advisory Action.

In direct contrast to *Cherukuri*, *Oppenheimer* and *Sturtz*, and as discussed above, the presently claimed products and methods provide the advantages of having a unique and additional flavoring agent. Appellants respectfully submit that because *Sturtz*, *Cherukuri*, and *Oppenheimer* fail to disclose or suggest each and every element of the present claims, the cited references fail to render the claimed subject matter obvious.

3. The Skilled Artisan Would Have No Reason to Combine the Cited References to Arrive at the Present Claims

Appellants further submit that, even if the references disclose every element of the prior claims, one of ordinary skill in the art would have no reason to combine the cited references because *Sturtz* teaches away from both *Cherukuri* and *Oppenheimer*, as well as the present claims. For example, *Sturtz* is entirely directed to providing as low a menthol content as possible while also providing peppermint-like organoleptic properties. See, *Sturtz*, column 2, lines 28-31. *Sturtz* specifically teaches that menthol is undesirable in ingestible products "because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium." See, *Sturtz*, column 2, lines 24-28 (emphasis added). In fact, *Sturtz* states that menthol is "substantially absent from the oil" and that "[t]he low menthol content of the essential oil is important" to avoid nasal and gastrointestinal problems. See, *Sturtz*, column 2, lines 24-26 and 28-31 (emphasis added).

In contrast, *Cherukuri* is entirely directed to an oral composition requiring both menthol and N-substituted-p-menthane carboxamide compound. See, *Cherukuri*, page 1, column 2, lines 34-38. *Cherukuri* specifically teaches that "[t]he presence of only one of these components will not provide the desired results," and that "[a] combination of these two ingredients when used in specific amounts overcomes the deficiencies of each component." See, *Cherukuri*, page 2,

column 2, lines 5-7 and lines 16-18. Similarly, the present claims require menthol in an oral consumable product.

Also in contrast to *Sturtz*, *Oppenheimer* is entirely directed to an oral composition containing a volatile oil such as menthol in combination with a sensorially undetectable amount of a volatile oil modifying agent. See, *Oppenheimer*, page 2, column 2, lines 5-12. *Oppenheimer* specifically teaches that menthol's "medicinal effect is known in the art," and that menthol "is useful to relieve local irritations in the throat and mouth." See, *Oppenheimer*, page 1, column 1, lines 45-48. This is directly antithetical to the proposition from *Sturtz*, which specifically teaches that menthol is undesirable in ingestible products "because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium." See, *Sturtz*, column 2, lines 24-28 (emphasis added). Thus, *Sturtz* expressly teaches away from using any menthol in ingestible products as disclosed by both *Cherukuri* and *Oppenheimer*, as well as the present claims.

The Examiner asserts that one of ordinary skill in the art would combine *Cherukuri*, *Oppenheimer*, and *Sturtz* "to use a flavor that will give the composition the taste of peppermint oil without adding additional menthol." See, final Office Action, page 6, lines 16-22. However, as discussed previously, the present claims require additional menthol in an oral consumable product. *Sturtz* teaches away from the use of any menthol in ingestible products, regardless of whether the menthol is used to give the composition the taste of peppermint. *Sturtz* expressly states that menthol, without any limitation as to what the menthol is used for, "irritates nasal, oral and gastrointestinal epithelium." See, *Sturtz*, column 2, lines 24-28 (emphasis added). As such, *Sturtz* teaches away from the use of any menthol in oral consumable products. Although the Erospicata oil of *Sturtz* may contain a very small amount of menthol (only 0.05%, which *Sturtz* describes as being "substantially absent" from the oil), *Sturtz* expressly teaches away from using any additional menthol apart from that present in the Erospicata oil. See, *Sturtz*, column 2, lines 24-34; Table 1. By expressly disparaging the use of menthol in ingestible products, *Sturtz* teaches away from using any additional menthol not already present in its Erospicata oil.

In the Advisory Action, the Examiner also states that *Cherukuri* "discloses the use of peppermint in combination with menthol. It would have been obvious to use Erospicata oil to obtain the flavor of peppermint without adding additional menthol." See, Advisory Action, page 3, lines 4-6. Appellants respectfully disagree, however, because peppermint oil provides additional levels of menthol to the already required amount of menthol, which *Sturtz* specifically

teaches away from. Further, *Cherukuri* provides no reason as to why the skilled artisan would want to substitute the peppermint in exchange for a less irritating product such as, for example, Erospicata. Indeed, *Cherukuri* fails to discuss any disadvantages with using peppermint or menthol other than the potential bitterness of menthol, as is admitted by the Examiner. See, Advisory Action, page 3, lines 3-4. Such a disadvantage would not lead the skilled artisan to use a less irritating flavoring agent such as Erospicata. Rather, such a disadvantage would lead the skilled artisan to find a less bitter flavoring agent.

The Examiner further states in the Advisory Action that *Sturtz* “does not teach away from adding menthol in ingestible products.” See, Advisory Action, page 3, lines 11-12. Appellants respectfully disagree and submit that, as discussed above, *Sturtz* specifically teaches that menthol is undesirable in ingestible products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28 (emphasis added). In fact, *Sturtz* states that menthol is “substantially absent from the oil” and that “[t]he low menthol content of the essential oil is important” to avoid nasal and gastrointestinal problems. See, *Sturtz*, column 2, lines 24-26 and 28-31 (emphasis added). As such, Appellants respectfully submit that it would not have been obvious to combine *Sturtz*, *Cherukuri* and *Oppenheimer* to arrive at the present claims.

In addition, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. See, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). For at least the reasons set forth above, Appellants respectfully submit that the skilled artisan would not have been able to predict the benefits achieved by the presently claimed oral products in view of the cited references. Indeed, because *Sturtz* teaches away from both *Cherukuri* and *Oppenheimer*, as well as the present claims, the skilled artisan would have no reason to expect or predict the benefits achieved by the present oral products. Instead, based upon a reading of the cited references (e.g., *Sturtz*), the skilled artisan would predict that the incorporation of menthol in ingestible products would lead to irritation of the nasal, oral and gastrointestinal epithelium.

Moreover, the Examiner cannot pick and choose specific teachings of the references to meet the claimed limitations but rather must consider the teachings of each reference as a whole. See, MPEP Section 2142 (2009). Regardless of which cooling agent one of ordinary skill in the art may choose, the fact remains that *Sturtz* as a whole expressly teaches away from using any

menthol in addition to that contained in its Erospicata oil. See, *Sturtz*, column 2, lines 24-28. Because *Oppenheimer* discloses that menthol may be used as a cooling agent and for its medicinal properties, Appellants respectfully submit that *Sturtz* expressly teaches away from *Oppenheimer*. Because *Cherukuri* specifically requires that menthol be used in order to achieve a longer lasting cooling sensation, Appellants respectfully submit that *Sturtz* expressly teaches away from *Cherukuri*. Because *Sturtz* is entirely directed to an oil with as low a menthol content as possible to avoid gastrointestinal and nasal irritation, *Sturtz* teaches away from adding menthol to an oral product as taught by *Cherukuri*, *Oppenheimer*, and the present claims.

In sum, the Examiner has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by [Appellants].” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998). Specifically, the Examiner has continued to ignore the express teaching in *Sturtz* that menthol is undesirable in oral products “because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium.” See, *Sturtz*, column 2, lines 24-28 (emphasis added). Because *Sturtz* teaches away from *Cherukuri*, *Oppenheimer*, and the present claims, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

Appellants respectfully submit that unless those portions of the art that teach away from the combination that is proposed are considered, almost every invention would be obvious, hence the reason the courts have time and time again cautioned against such a hindsight analysis. Therefore, Appellants respectfully submit that the Examiner has improperly applied hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellants respectfully submit that such a reason is not present in the instant case.

Additionally, the Federal Circuit has specifically found that references are not properly combinable or modifiable if their intended purpose is destroyed. For instance, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended

purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). This certainly applies where *Cherukuri* is not concerned with reducing the amount of menthol used in the compositions since the entire purpose of the composition is for long-lasting non-bitter cooling flavor as provided by the addition of a N-substituted-p-menthane carboxamide compound to menthol, where menthol is a necessary component in order to achieve the long-lasting non-bitter cooling flavor. As such, any composition of *Cherukuri* would render the Erospicata disclosed in *Sturz* useless because *Sturz* is directed to the use of a "substantially absent" amount of menthol contained in its Erospicata oil. See, *Sturtz*, column 2, lines 24-26. For at least these reasons, Appellants respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

For at least the reasons discussed above, the combination of *Cherukuri* in view of *Oppenheimer* and *Sturtz* is improper, fails to disclose or suggest every element of the present claims and, thus, fails to render the claimed subject matter obvious. Additionally, *Sturtz* teaches away from adding menthol to an oral product as taught by *Cherukuri*, *Oppenheimer*, and the present claims. Moreover, the cited references fail to recognize the advantages, benefits and/or properties of the oral products in accordance with the present claims. Therefore, one of ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

Accordingly, Appellants respectfully request that the obviousness rejections with respect to Claims 1, 4, 7-11, 14, 18-20 and 27-33 be reconsidered and withdrawn.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejections of Claims 1, 4, 7-11, 14, 18-20 and 27-33. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge \$540 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712038-00306 on the account statement.

Respectfully submitted,

~~K&L GATES LLP~~

BY

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Dated: October 27, 2010

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/705,481

1. A consumable oral product comprising Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total consumable oral product, and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

4. The consumable oral product of Claim 1 wherein the heating agent is present in an amount of from about 0.01% to about 2.0% by weight of the total consumable oral product.

7. The consumable oral product of Claim 1 wherein the product is selected from the group consisting of chewing gum, dentifrice, confection, lozenge, mouthwash, mouth spray, and edible film.

8. The consumable oral product of Claim 1 wherein the Erospicata oil is present as a flavoring agent.

9. The consumable oral product of Claim 8 wherein the flavoring agent comprises 0.05 to 5% by weight of the total consumable oral product.

10. The consumable oral product of Claim 8 wherein Erospicata oil comprises 5 to 70% by weight of the total flavoring agent.

11. A chewing gum product comprising Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product, and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

14. The chewing gum product of Claim 11 wherein the cooling agent is present in an amount of from about 0.01% to about 2.0% by weight of the total chewing gum product.

18. The chewing gum product of Claim 11 wherein the Erospicata oil is present as a flavoring agent.

19. The chewing gum product of Claim 18 wherein the flavoring agent comprises 0.05 to 5% by weight of the total chewing gum product.

20. The chewing gum product of Claim 18 wherein Erospicata oil comprises 5 to 70% by weight of the total flavoring agent.

27. A method of enhancing a flavor in an oral consumable product comprising the steps of adding to a consumable oral product Erospicata oil, menthol, a heating agent and a cooling agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total oral consumable product, and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

28. The method of Claim 27 wherein the oral consumable product is selected from the group consisting of chewing gum, dentifrice, confection, lozenge, mouthwash, mouth spray, and edible film.

29. The method of Claim 27 wherein the Erospicata oil is present as a flavoring agent.
30. The method of Claim 29 wherein the flavoring agent comprises 0.05 to 5% by weight of the total oral consumable product.
31. The method of Claim 29 wherein Erospicata oil comprises 5 to 70% by weight of the total flavoring agent.
32. A method of producing a chewing gum product comprising the steps of adding to a composition that includes a gum base, Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total chewing gum product, and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.
33. A method of reducing the amount of peppermint flavor required to achieve an organoleptic effect in a product comprising the steps of manufacturing the product with Erospicata oil, menthol, a cooling agent and a heating agent, wherein the Erospicata oil comprises about 0.01% to about 5% by weight of the total product, and wherein the heating agent is chosen from the group consisting of capsicum oleoresin, capsaicin, piperine, gingerol, shoagol, cinnamic aldehyde, ginger oleoresin, cinnamon oleoresin, and cassia oleoresin, black pepper oleoresin, pepper oleoresin and combinations thereof.

EVIDENCE APPENDIX

EXHIBIT A: Non-final Office Action dated August 5, 2009

EXHIBIT B: Final Office Action dated March 5, 2010

EXHIBIT C: Advisory Action dated August 11, 2010

EXHIBIT D: U.S. Patent No. 5,009,893 to Cherukuri et al. ("*Cherukuri*")

EXHIBIT E: U.S. Patent No. 4,980,169 to Oppenheimer et al. ("*Oppenheimer*")

EXHIBIT F: U.S. Plant Patent No. 8,645 to Sturtz ("*Sturtz*")

RELATED PROCEEDINGS APPENDIX

None.

EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22315-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,481

11/10/2003

Souya S. Johnson

112703-306

5154

29156

7590

08/05/2009

K&L Gates LLP

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

08/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/705,481	JOHNSON ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7-11, 14, 18-21 and 24-33 is/are pending in the application.
 4a) Of the above claim(s) 21 and 24-26 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1, 4, 7-11, 14, 18-20 and 27-33 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-848) | Paper No(s)/Mail Date, _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments in the Appeal Brief, filed April 30, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a "cooling agent" and the instant specification defines "cooling agent" as a "non-menthol cooling agent". The specification further discloses that the cooling agents used in the

instant invention may be chosen from "menthol, menthol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butanamide and menthyl glutarate or combination thereof (page 4, lines 3-5). The term "cooling agent" lacks "Written Description" because it is specifically defined as not being a menthol and then is disclosed as encompassing menthol, which makes the term confusing and contradictory.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The claims recite "an effective amount of menthol, a cooling agent and a heating agent". The phrase is indefinite insofar as it is unclear if "effective amount" encompasses only the amount of "menthol" or if it encompasses "menthol, a cooling agent and a heating agent" combined. It is also not clear what "menthol" or the combination of "menthol, a cooling agent and a heating agent" are effective for, such as for an antimicrobial effect or an improved flavor experience.

2) The claims recite "cooling agent" and the specification defines "a cooling agent" as "non-menthol cooling agents" (page 1, lines 20 and 21). The instant

specification further discloses a cooling agent is chosen from "menthol, menthol glyceryl ether...". The term "cooling agents" has conflicting definitions and is therefore indefinite insofar as it is unclear whether "cooling agents" encompass menthol or not.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1, 4, 7-11, 14, 18-20 and 27-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kumamoto et al. (US 2002/0119231) in view of Sturtz (US Plant 8,645). The rejection is maintained.

Applicant's Arguments

Applicant argues that the combination of Kumamoto et al. and Sturtz do not disclose or suggest every element of the presently pending claims. The combination recited in the instant claims provides a novel flavor and reduces the cost of peppermint flavored products. The reference also fails to disclose menthol in an "effective amount". Sturtz discloses Erospicata oil contains 0.05% menthol and not 1% menthol. This amount is not effective within in the meaning of the present claims. Further Sturtz is directed to as low as a menthol content possible and would not include an effective amount of menthol. Kumamoto et al. fail to disclose using a combination of menthol and a non-menthol cooling agent. The references also fail to disclose an oral product comprising Erospicata at a concentration ranging from about 0.01 to about 5% by weight of the total product. Nowhere in Sturtz or Kumamoto et al. does it disclose that Erospicata oil is used to achieve a novel flavor when combined with a cooling agent.

Sturtz merely discloses that Erospicata oil has a characteristic peppermint taste and smell. Sturtz also teaches away from the instant claims and Kumamoto et al. because it teaches menthol is undesirable in ingestible products. Thus, one of skill of the art would not add additional menthol and the menthol contained in the Erospicata oil is not an effective amount. Because Sturtz does not teach how much is too much menthol and teaches that menthol causes nasal and gastrointestinal irritation, one would not be motivated to add any menthol to oral compositions. These arguments are not persuasive.

Examiner's Response

The Examiner asserts that the combination of references suggest every element of the pending claims because Kumamoto et al suggest using a combination of a cooling agent and a warming agent in compositions with a peppermint flavor and Sturtz provides motivation of why one of skill in the art would want to use Erospicata oil as a peppermint flavor. The compositions of Kumamoto provide the teaching of a "novel flavoring" because the flavoring having a warming effect is the disclosed invention. In regards to the "effective amount", there appears to be no indication in the instant specification of what encompasses an "effective amount" or what the menthol is effective against. Sturtz discloses menthol is present in the Erospicata oil and comprises a maximum of 1% of the oil. Although there is no example disclosed by the reference that the oil comprises about 1%, the reference does teach that the oil

comprises more than 0.05% by its disclosure of menthol comprising 0.17% by weight (see Table 2). This shows that the amount of menthol may vary. Although Sturtz teaches the absence of menthol avoids irritation to the oral and nasal cavities, the oil itself comprises menthol and therefore meets the limitations of the instant claims, considering it is not disclosed what "an effective amount" encompasses (see Indefiniteness Rejection above). Further, Sturtz provides several reasons why one would use erospicata oil, the first, to avoid too much menthol when this is desired and second, to avoid the bitter taste due to piperitone when this is desired. When certain amounts of menthol and a strong peppermint taste without the bitter taste of piperitone are desired, one of skill in the art would be motivated to use Erospicata oil to avoid the bitter taste. Also since it is disclosed in the art that menthol is an agent used separate from peppermint, as disclosed by Kumamoto, it would have been reasonable for one of skill in the art to add an "effective amount" of menthol dependent on its desired function.

In regards to the amount of Erospicata oil, the oil provides flavoring to the compositions and therefore it would have been taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of erospicata oil in the flavor composition motivated by the desire to achieve optimum flavor in the oral composition.

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected.

Claims 21 and 24-26 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,481

11/10/2003

Sonya S. Johnson

112703-306

5154

29156 7590 03/05/2010
K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

03/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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chicago.patents@kigates.com

Office Action Summary	Application No.	Applicant(s)	
	10/705,481	JOHNSON ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

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Period for Reply

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- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7-11, 14, 18-21 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7-11, 14, 18-21 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of.
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed November 3, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed November 3, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The deleted material which is not supported by the original disclosure is as follows: the specification discloses "In an embodiment, a chewing gum comprising Erospicata oil and cooling agent selected from the group consisting of menthol, menthol glyceryl ether, N,2,3-trimethyl-2-isopropyl-butamide and menthyl glutamate or combinations thereof". Although Applicant has deleted this paragraph in order to clarify the definition of "cooling agent", which is defined as non-menthol cooling agents, yet Applicant has not only deleted the menthol cooling agents but also those that are not encompassed by menthol and therefore it appears the deletion of N,2,3-trimethyl-2-isopropyl-butamide

and menthyl glutamate, which appear to be non-menthol cooling agents, appears to be "New Matter".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims

Claim Rejections - 35 USC § 112 – Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation wherein the menthol comprises at least 0.02% by weight". The specification does not appear to support this limitation because the recitation of "at least" supports amounts various amounts greater than 0.02 and the specification only appears to support menthol with a concentration of 0.02%, 0.03% and 0.1 to 20% in the case of edible film formulations. Thus, the limitation appears to be "New Matter".

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (US 5,009,893) in view of Oppenheimer et al. (US 4,980,169) and Sturtz (US Plant 8,645).

Cherukuri et al. disclose edible compositions capable of providing long-lasting, breath freshening perception without bitterness which comprises using a cooling agent comprising menthol and an N-substituted-p-methane carboxamide compound (Abstract). Menthol comprises 5 to 70% by weight of the cooling composition and the N-substituted-p-methane carboxamide compound comprises 30 to 95% of the cooling composition. The cooling composition comprises 0.01 to about 2.0% of the product composition (col. 4, lines 17-38). The cooling compositions may be added to chewing gums (col. 5, lines 30-35). Flavor oils may be added to the compositions (col. 6, lines 18-20). Peppermint comprises 1.1438% of the composition (Table 1).

The reference differs from the instant claims insofar as it does not disclose one of the warming agents recited in the instant claims or that the compositions comprise erospicata oil.

Oppenheimer et al. disclose confections containing a volatile oil. The compositions contains a sensorially undetectable amount of a volatile oil modifying agent which enhances the flavor of the volatile oil as well as ameliorates the perception of unpleasant organoleptic sensation such as bitterness initiated by the volatile oil being released in the oral cavity. The modifying agent is preferably the oleoresin form of capsicum (see Abstract). The compositions comprise both menthol and eucalyptus,

which is also a cooling agent, as the volatile oil components (col. 4, lines 14-20). Other volatile oil components include peppermint oil and extracts derived from other plants (col. 6, lines 10-20). The volatile oil comprises 0.05 to about 1.0% by weight of the confection (see claim 5). Other additives such as flavors, colorants and the like may also be added to the compositions (col. 4, lines 51-53). Additional flavors include natural and artificial flavors such as peppermint and various fruit flavors (col. 6, lines 59-65). The modifying agent may comprise 1 to 150 parts per million by weight of the product (col. 3, lines 10-16), which translates to 0.0001 to 0.015%, encompassing claim 4.

The reference differs from the instant claims insofar as it does not disclose erospicata oil in the recited amount is present in the compositions or that the composition is a chewing gum.

It would have been obvious to one of ordinary skill in the art to have used a warming agent such as capsicum oleoresin in the compositions of Cherukuri et al. motivated by the desire to insure the perception of unpleasant organoleptic sensation such as bitterness was ameliorated as well as enhance the flavor of the cooling agents, as disclosed by Oppenheimer et al.

The combination of Cherukuri et al. and Oppenheimer et al. differs from the instant claims insofar as it does not disclose using erospicata oil in the compositions.

Sturtz teaches a new mint plant species named Erospicata and has the same organoleptic properties as peppermint oil (col. 2, lines 21-23). The reference teaches Erospicata has a characteristic peppermint taste and smell, yet its oil contains much

lower levels of menthol and much higher levels of menthone, less than 1%. The low menthol content of the essential oil is important because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium, therefore only very small amounts of conventional peppermint oil can be added to ingestible products such as candy. The menthone content provides a "hot" peppermint taste and odor. The absence of this alcohol helps avoid nasal and gastrointestinal irritation, while the menthone provides peppermint-like organoleptic properties. The mint plant also expresses an oil that is low in carvone and piperitone content. The substantial absence of carvone and piperitone is important because these substances provide a taste that is organoleptically undesirable in peppermint oil. Carvone provides a spearmint taste, while piperitone imparts a bitter taste (col. 2, lines 5-36).

The reference differs from the instant claims insofar as it does not teach consumable products such as chewing gums comprising a cooling agent, a heating agent or a method of enhancing the flavor of an oral product by adding Erospicata and a cooling agent or heating agent.

It would have been obvious to one of ordinary skill in the art to have used erospicata as a flavor in place of or in addition to peppermint in the disclosed amount of 1.1438 in the compositions of Cherukuri et al. in view of Oppenheimer et al. motivated by the desire to use a flavor that will give the composition the taste of peppermint oil without adding additional menthol that would lead to irritation or would lead to a bitter taste due to the additional menthol as disclosed by Sturtz.

In regards to claims 27-31, when Erospicata is added to the consumable compositions, it may be added in higher amounts to enhance or add more peppermint flavor without the effects of menthol. In regards to the claims 32-33, it would have been obvious to reduce the amount of peppermint originally used in the gum composition because the addition of erospicata can provide similar effects, e.g., flavor and organoleptic effects, without the irritation of extra menthol.

In regard to the amount of warming agent in claim 4, the prior art does not disclose the exact claimed values 0.1% to about 2.0%, but does overlap, 0.0001% to 0.015%: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claims 1, 4, 7-11, 14, 18-20 and 27-33 are rejected.

Claims 21 and 24-26 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

Notice of References Cited

Application/Control No.

10/705,481

Applicant(s)/Patent Under
Reexamination
JOHNSON ET AL.

Examiner

LEZAH W. ROBERTS

Art Unit

1612

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,980,169	12-1990	Oppenheimer et al.	424/439
*	B	US-5,009,893	04-1991	Cherukuri et al.	424/440
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

* A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EXHIBIT C



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,481	11/10/2003	Sonyn S. Johnson	3712038.00306	5154
29156 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 08/11/2010		EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			NOTIFICATION DATE 08/11/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@kigates.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/705,481	Applicant(s) JOHNSON ET AL.
Examiner LEZAH W. ROBERTS	Art Unit 1612

-The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

THE REPLY FILED 06 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): The rejection under 35 USC 112 -Written Description (New Matter).
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____
 Claim(s) objected to: _____
 Claim(s) rejected: 1,4,7-11,14,18-20 and 27-33
 Claim(s) withdrawn from consideration: 21 and 24-26.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/Lezah W Roberts/
Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because: In regard to Applicant's arguments, Sturtz does not necessarily teach away from Cherukuri and Oppenheimer. Cherukuri requires the combination of menthol and a carboxamide cooling agent because the combination provides a heightened cooling sensation. Cherukuri also discloses that menthol tends to distort flavor notes and render the product bitter when not used in precise amounts (col. 4, lines 8-13). The reference also discloses the use of peppermint in combination with menthol. It would have been obvious to use Erospicata oil to obtain the flavor of peppermint without adding additional menthol in order to better control the amount of menthol that is incorporated into the compositions. Thus one would be able to obtain the desired cooling effect without having to factor in the amount of menthol included by peppermint. One would also be able to control the peppermint flavor without contemplating how the additional menthol from the peppermint oil would affect the composition. In regard to Oppenheimer, it provides the motivation as why one of ordinary skill in the art would want to add warming agent to the compositions of Cherukuri. Although Sturtz teaches menthol irritates nasal, oral and gastrointestinal epithelium, it does not teach away from adding erospicata oil to a composition requiring menthol and having a flavoring agent such as peppermint. It also does not teach away from adding menthol in ingestible products, it teaches there are some negative effects of adding menthol to ingestible products. It also suggests an alternative for peppermint oil when either menthol is not required and a strong peppermint taste is, or a strong peppermint taste is required and a certain amount of menthol is desired such as when menthol is used for its health benefits. Further, since Cherukuri teaches the amount of menthol is important to the taste of the composition, it would be reasonable for one of ordinary skill in the art to substitute peppermint oil with erospicata oil to avoid too much menthol. Additionally, it would be reasonable to use erospicata in place of peppermint to achieve the peppermint taste as well as add a degree of control of how much menthol is used in a composition requiring it. Sturtz does not appear to be teaching away from "any" menthol because the plant itself has menthol. In regard to considering Sturtz as a whole, one of ordinary skill in the art would take in consideration Sturtz's teaching of menthol, but would also recognize the advantages of using Erospicata oil with compositions requiring both menthol and peppermint oil, such as those stated above.

EXHIBIT D

[54] **BREATH-FRESHENING EDIBLE
COMPOSITIONS OF METHOL AND A
CARBOXAMIDE**

[75] Inventors: Subraman R. Cherukuri, Towaco;
Krishna Raman, Randolph, both of
N.J.; Gul Mansukhani, Staten Island,
N.Y.; Ralph Clifrese, Wharton, N.J.;
Lucy L. Wong, Jackson Heights,
N.Y.

[73] Assignee: Warner-Lambert Company, Morris
Plains, N.J.

[21] Appl. No.: 381,218

[22] Filed: Jul. 17, 1989

[51] Int. Cl.³ A61K 7/16; A61K 9/68

[52] U.S. Cl. 424/440; 424/48;
424/49; 424/441

[58] Field of Search 424/440, 48, 49, 441

[56] References Cited

U.S. PATENT DOCUMENTS

2,525,072 10/1950 Kearby 167/93

2,922,747 1/1960 Scanlan 167/93
3,554,767 1/1971 Daum 424/440 X
4,029,759 6/1977 Humbert 424/49
4,060,091 11/1977 Watson et al. 131/9
4,112,066 9/1978 Hussein 424/48
4,136,163 1/1979 Watson et al. 424/34
4,724,151 2/1988 Mansukhani et al. 426/3
4,853,212 8/1989 Faust 424/48 X

FOREIGN PATENT DOCUMENTS

989738 5/1976 Canada .
2127005 1/1972 France .
1351761 5/1974 United Kingdom .

Primary Examiner—Thurman K. Page
Attorney, Agent, or Firm—Daniel A. Scolia, Jr.

[57]

ABSTRACT

An edible composition capable of providing long-lasting, breath freshening perception without bitterness which comprises using in said edible composition a cooling composition comprising methanol and an N-substituted-p-methane carboxamide compound.

30 Claims, 3 Drawing Sheets

MENTHOL (ML) AND CARBOXAMIDE (M)

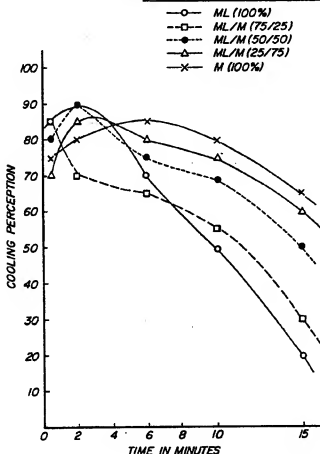


FIG-1

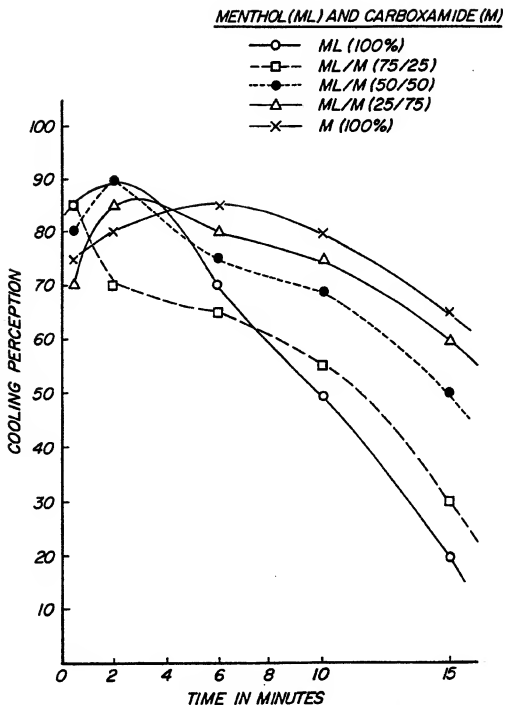


FIG-2

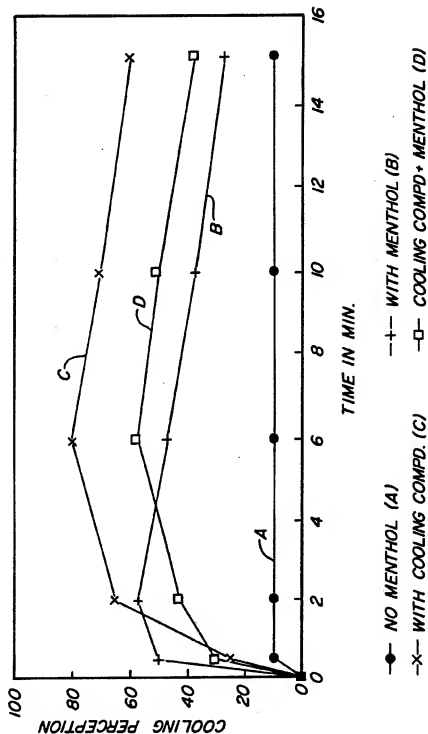
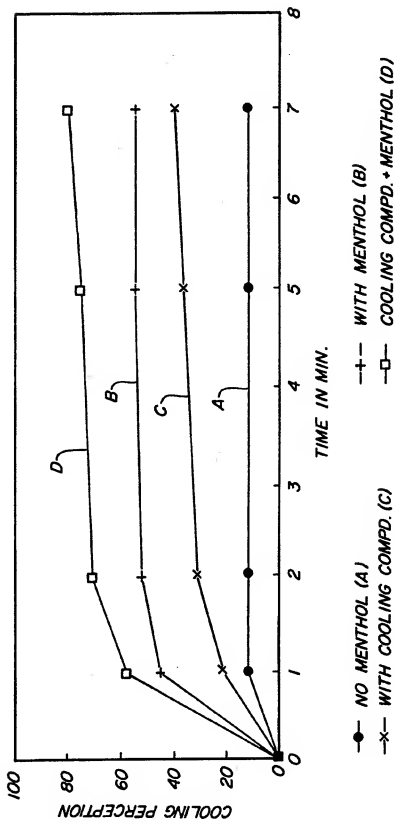


FIG-3



BREATH-FRESHENING EDIBLE COMPOSITIONS OF METHOL AND A CARBOXAMIDE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to edible compositions having a unique, long-lasting, cooling perception which provides the user with a significantly enhanced perception of breath-freshening without bitterness and more particularly to chewing gum compositions and confectionery compositions which provide a long-lasting, breath freshening perception without bitterness.

2. Description of Related Art

It is well recognized that one of the purposes of chewing gum and confectionery products is to enhance one's breath and provide a clean, cool, fresh feeling in the mouth. Most products can provide at least marginal enhancement of the breath for the first few minutes while the flavor is the most intense, but lack the ability to maintain such perception for long periods of time, that is times up to about 30 minutes.

Chewing gums in particular have not been able to deliver to the user sufficient flavor such that there is a perceived breath-freshening effect which is sustained over a long period of time. In some instances, the incorporation of greater than normal amounts of mint flavor have been attempted to induce the breath-freshening effect, but harsh and bitter tones often result. Such bitterness has been attributed to the presence of menthol when either used alone or when present in the flavor oil. Harsh tones, of course, are unacceptable to the consumer, who requires an organoleptically pleasing taste. Larger amounts of flavor are also a disadvantage in that the oils tend to plasticize the gum base, thereby altering the texture and consistency of the chewing gum product. In non-stick chewing gum compositions, flavor plasticization of the gum base can defeat the non-stick character, rendering the gum unacceptable to denture and prosthesis wearers. For these reasons, the simple addition of higher levels of mint flavor will not provide a satisfactory chewing gum having enhanced breath-freshening.

Numerous patents have discussed the combination of flavor oils and flavor powders to increase flavor impact and extend the taste over a prolonged period of time. Such techniques as encapsulation of flavors and sweeteners to provide time release are commonly used to achieve prolonged effects and sequential delivery of the flavor or sweetener.

The patents which do address the concept of breath-freshening often focus on the incorporation of an additive which serves as a deodorizer. For example, U.S. Pat. No. 2,525,072 discloses chewing gums containing inorganic silicone and magnesium powders which serve as absorbents of malodor. U.S. Pat. No. 2,922,747 discloses the use of chlorophyll, vegetable oils (lipids) and lecithin as effective deodorants in tablets and chewing gum compositions.

Canadian Pat. No. 989,738 discloses a wafer containing cetyltrimethylbenzylammonium chloride and peppermint oil as a means for providing residual breath-sweetening in the mouth. In contrast U.S. Pat. No. 4,112,066 discloses breath-freshening compositions containing calcium and magnesium carbonate in combination with copper gluconate in a mint flavored tablet. Whereas French Demande 2,127,005 discloses reodorizing compositions containing 10-2000 ppm alpha-

ionone, alpha-methylionone, citral or geranyl formate as a means of masking odor.

Besides these approaches, U.S. Pat. No. 4,724,151 entitled "Chewing Gum Compositions Having Prolonged Breath-Freshening", concerns a mint flavored chewing gum composition capable of providing improved breath-freshening perception comprising a blend of 1) a liquid flavor oil selected from the group consisting of spearmint oil, peppermint oil and mixtures thereof, wherein the flavor oil has a menthol content of about 27% to about 36% by weight of said flavor oil; 2) a spray-dried flavor oil selected from the group consisting of peppermint oil and spearmint oil and mixtures thereof; and 3) spray-dried menthol present in amounts of about 0.2 to about 0.75% by weight of the chewing gum composition. This invention focused on mint-flavored gums and confectionery, i.e., peppermint, spearmint and combinations thereof, because of their association with the cooling sensation in the mouth and their ability to be combined with menthol to produce a sustained cooling sensation and fresh impact.

In addition to these procedures, U.S. Pat. No. 4,136,163 discloses the formation of a compound having the property of stimulating the cold receptors of the nervous system to produce cold sensations which compounds are disclosed for use in a variety of edible and topical preparations. The compounds disclosed are N-substituted-p-menthane-3-carboxamides which are the same compounds used by Applicants in the present invention.

SUMMARY OF THE INVENTION

Applicants have unexpectedly found that N-substituted-p-menthane carboxamides when used in combination with menthol in specific amounts results in an unexpected heightened cooling sensation in edible products. The use of either of these products alone or outside the disclosed ranges fail to result in the cooling effect achieved herein.

In accordance with a preferred embodiment of the present invention, a chewing gum composition which is capable of providing long-lasting, breath freshening perception without bitterness comprises a gum base, a sweetener and a cooling composition comprising menthol and an N-substituted-p-menthane carboxamide of the formula:



wherein, R₁ when taken separately is selected from the group consisting of hydrogen and an aliphatic radical containing up to 25 carbon atoms;

R₂, when taken separately is selected from the group consisting of hydroxy radical, and an aliphatic radical containing up to 25 carbon atoms, with the proviso that when R₁ is hydrogen R₂ may also be an aryl radical of up to 10 carbon atoms and selected from substituted phenyl, phenalkyl, naphthyl and substituted naphthyl, and pyridyl; and

R_1 and R_2 when taken together, represent a cyclic or heterocyclic group of up to 25 carbon atoms.

Another preferred embodiment of the present invention is a confectionery composition which is capable of providing long-lasting, breath freshening perception without bitterness comprising a confectionery matrix and a cooling composition comprising menthol and an N-substituted-p-methane carboxamide of the formula:



wherein R_1 when taken separately is selected group consisting of hydrogen and an aliphatic radical containing up to 25 carbon atoms;

R_2 when taken separately is selected from the group consisting of hydroxy radical, and an aliphatic radical containing up to 25 carbon atoms, with the proviso that when R_1 is hydrogen R_2 may also be an aryl radical of up to 10 carbon atoms and selected from substituted phenyl, phenalkyl, naphthyl and substituted naphthyl, and pyridyl; and

R_1 and R_2 when taken together, represent a cyclic or heterocyclic group of up to 25 carbon atoms.

Another embodiment involves a process of preparing a chewing gum composition capable of imparting breath freshening perception which comprises admixing a chewing gum base at a temperature of about 70° C. to about 120° C. with a softener to obtain a homogenous pliable mixture; continuing to mix while adding a sweetening agent; adding menthol and a N-substituted-p-methane carboxamide compound and the remaining chewing gum ingredients and mixing until a uniform mass is obtained; and thereafter forming the mixture into suitable shapes.

Another embodiment involves a process for preparing a confectionery composition capable of imparting breath freshening perception which comprises (a) preparing a soft confectionery matrix; (b) adding menthol and a N-substituted-p-methane carboxamide compound to the matrix, and mixing until a uniform mass is obtained; and (c) thereafter forming the mixture into suitable confectionery shapes.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 graphically depicts the breath-freshening perception achieved from the sensory evaluation studies of Example 1 formulations.

FIG. 2 graphically depicts the breath-freshening perception achieved from the sensory evaluation studies of Example 2 formulations.

FIG. 3 graphically depicts the breath-freshening perception achieved from the sensory evaluation studies of Example 3 formulations.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

It has been unexpectedly discovered that the use of a particular cooling compound in combination with menthol results in the formation of an edible product which exhibits a high initial cooling perception as well as long-lasting, breath-freshening for times as long as 30 minutes. This combination of ingredients may be used in both

sugared and sugarless products to achieve this heightened perception.

While the precise reason why these agents give an enhanced breath-freshening effect is not entirely understood, it is known that each component plays a vital role. The presence of only one of these components will not provide the desired results and as such are not considered part of this invention. Menthol, when used alone, has an initial high flavor impact, but its impact drops sharply within a few minutes after use. In addition, it tends to distort flavor notes and render the product bitter when not used in precise amounts. In contrast, N-substituted-p-methane carboxamides disclosed in U.S. Pat. No. 4,136,163 fail to exhibit any initial cooling perception.

A combination of these two ingredients when used in specific amounts overcomes the deficiencies of each component. The cooling composition of the present invention contains menthol in amounts of about 5 to about 70% by weight and preferably in amounts of about 20 to about 60% by weight of the cooling composition. The N-substituted-p-methane carboxamide compound is used in amounts of about 30 to about 95% by weight and preferably in amounts of about 40 to about 80% by weight of the cooling composition. It is critical that the amount of the N-substituted-p-methane carboxamide compound not be below 30% by weight of the combination, since such low amounts fail to form products that exhibit long-lasting cooling which are not bitter. In contrast, amounts above about 95% fail to form products that exhibit an initial cooling effect.

The cooling composition is used in the formulations of the invention in amounts from about 0.01 to about 2.0% by weight of the total formulation and preferably in amounts of about 0.1 to about 0.5% by weight of the total formulation.

The N-substituted-p-methane-carboxamides used in the invention are those that fall within the formula:



wherein R_1 when taken separately is selected from the group consisting of hydrogen and an aliphatic radical containing up to 25 carbon atoms;

R_2 when taken separately is selected from the group consisting of a hydroxy radical, an aliphatic radical containing up to 25 carbon atoms, with the proviso that when R_1 is hydrogen R_2 may also be an aryl radical of up to 10 carbon atoms and selected from substituted phenyl, phenalkyl, naphthyl and substituted naphthyl, and pyridyl; and

R_1 and R_2 when taken together, represent a cyclic or heterocyclic group of up to 25 carbon atoms. These compounds are recited in U.S. Pat. No. 4,136,163, which disclosure is incorporated by reference herein.

A preferred species is N-ethyl-p-methane-3-carboxamide. It should be noted that these compounds are quite similar structurally to menthol itself.

While the carboxamide compounds are generally insoluble in water, they may be employed in the edible formulations as particulate solids and added directly to the formulations or blended with other solid ingredients used to make the compositions. It is contemplated that this component may be added in several forms, such as in the form of an encapsulate, or previously dissolved in a polar solvent and/or mixed with a flavor oil and then used in the inventive formulation. Encapsulation may be achieved using conventional procedures which do not constitute a part of this invention. The encapsulation may be performed using water-insoluble as well as water-soluble agents. This procedure is beneficial when a delay in cooling perception is desired. When the carboxamides are dissolved in a polar solvent such solvents may be selected from a wide variety of materials. Preferred solvents are selected from the group consisting of ethyl alcohol, ethylacetate, diethyl ether, isopropyl alcohol and glycerin which have dipole moments in Debyes of 1.69, 1.78, 1.15, 1.66 and 2.56 respectively. The use of a solvent is particularly preferred when preparing confectionery products in order to obtain a uniform mixture of the compound into the confectionery matrix. In chewing gums which employ glycerin, the compound may be simply preblended in the glycerin and added simultaneously therewith to the product. The same is also effective when premixed in the flavor oil. Such premixtures aid in enhancing uniform distribution in the product and efficient release during use.

Chewing gum formulations in which the novel flavor compositions may be employed, will vary greatly depending on various factors such as the type of base used, consistency desired and other components used to make the final product. In general, useful amounts of gum base vary from about 5% to about 75% by weight of the final chewing gum composition, with preferred amounts being about 15% to about 30% by weight and most preferably about 15% to about 25%. The gum base may be any water-insoluble gum base well known in the art, providing it allows for adequate release of the two components such that breath-freshening is perceived. Illustrative examples of suitable polymers in gum bases include both natural and synthetic elastomers and rubbers. For example, those polymers which are suitable in gum bases, include, without limitation, substances of vegetable origin such as chicle, jelutong, gutta, percha, and crown gum. Synthetic elastomers such as butadiene-styrene copolymers, isobutylene-isoprene copolymers, polyethylene, polyisobutylene and polyvinyl-acetate and mixtures thereof, are particularly useful.

The instant invention is especially useful in gum bases which can be formulated into sugar and sugarless chewing gum and bubble gum compositions.

The gum base composition may contain elastomer solvents to aid in softening the rubber component. Such elastomer solvents may comprise methyl, glycerol or pentaerythritol esters of rosin or modified rosins, such as hydrogenated, dimerized or polymerized rosins or mixtures thereof. Examples of elastomer solvents suitable for use herein include the pentaerythritol ester of partially hydrogenated wood rosin and partially hydrogenated wood rosin, pentaerythritol ester of wood rosin, glycerol ester of wood rosin, glycerol ester of partially dimerized rosin, glycerol ester of polymerized rosin, glycerol ester of tall oil rosin, glycerol ester of wood rosin and partially hydrogenated wood rosin and the partially hydrogenated methyl ester of rosin, such as

polymers of alpha-pinene or beta-pinene, terpene resins including polyterpene and mixtures thereof. The solvent may be employed in an amount ranging from about 10% to about 75% and preferably about 45% to about 70% by weight to the gum base.

A variety of traditional ingredients such as plasticizers or softeners such as lanolin, stearic acid, sodium stearate, potassium stearate, glyceryl triacetate, glycerine and the like, and waxes, for example, natural waxes, petroleum waxes such as polyurethane waxes, paraffin waxes and microcrystalline waxes may also be incorporated into the gum base to obtain a variety of desirable textures and consistency properties. These individual additional materials are generally employed in amounts of up to about 30% by weight and preferably in amounts of from about 3% to about 20% by weight of the final chewing gum composition.

The chewing gum composition may also include conventional additives such as flavoring agents; coloring agents such as titanium dioxide; emulsifiers such as lecithin and glyceryl monostearate; and additional fillers such as aluminum hydroxide, alumina, aluminum silicates, calcium carbonate, and talc. Combinations of these conventional additives are contemplated. These fillers may also be used in the gum base in various amounts. Preferably the amount of fillers when used will vary from about 4% to about 45% by weight of the final chewing gum composition.

The present invention contemplates the inclusion of those sweeteners well known in the art, including both natural and artificial sweeteners. Thus, sweeteners may be chosen from the following non-limiting list: sugars such as sucrose, glucose (corn syrup), dextrose, invert sugar, fructose, and mixtures thereof; saccharin and its various salts such as the sodium or calcium salt; cyclamic acid and its various salts such as the sodium salt (cyclamates); the dipeptide sweeteners such as aspartame and Alitame; chlorinated sugar derivatives such as Sucralose; natural sweeteners such as dihydrochalcone; glycyrrhizin; Stevia rebaudiana (Stevioside); and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like. Also contemplated as a sweetener is the nonfermentable sugar substitute hydrogenated starch hydrolyzate (Icyasin) which is described in U.S. Pat. No. Re. 26,959. Also contemplated is the synthetic sweetener 3,6-dihydro-6-methyl-1,2,3-oxathiazin-4-one-2, 2-dioxide particularly the potassium (Aceulfame-K), sodium and calcium salts thereof as described in German Pat. No. 2,001,017.

The colorants useful in the present invention, include the pigments such as titanium dioxide, and are incorporated in amounts of up to about 10% by weight, and preferably up to about 6% by weight. Colorants may also include dyes suitable for food, drug and cosmetic applications. These colorants are known as F.D. & C. dyes. The materials acceptable for the foregoing spectrum of use are preferably water-soluble. Illustrative examples include indigo dye, known as F.D. & C. Blue No. 2, which is the disodium salt of 5,5'-indigotin-disulfonic acid. Similarly, the dye known as F.D. & C. Green No. 1, comprises a triphenylmethane dye and is F.D.&C. and D.&C. colorants and their corresponding chemical structures may be found in the Kirk-Othmer Encyclopedia of Chemical Technology, in Volume 5, at pages 857-884.

The cooling composition of the instant invention may also be used in conventional soft and hard confections.

The preparation of soft confections, such as nougat, involves conventional methods, such as the combination of two primary components, namely (1) a high boiling syrup such as corn syrup or the like and (2) a relatively light textured frappe, generally prepared from gelatin, egg albumen, milk proteins such as casein, and vegetable proteins such as soy protein, and the like. The frappe is generally relatively light, and may, for example, range in density from about 0.5 to 0.7.

The high boiled syrup of the soft confectionery is relatively viscous and possesses a higher density and frequently contains a substantial amount of sugar. Conventionally, the final nougat composition is prepared by the addition of a high boiled syrup to the frappe under agitation, to form the basic nougat mixture. Further ingredients such as flavoring, additional sugar, colorants, preservatives, medicaments, mixtures thereof and the like may be added thereafter also under agitation. General discussion of the composition and preparation of nougat confections may be found in B.W. Minifie, *Chocolate, Cocoa and Confectionery Science and Technology*, 2nd edition, AVI Publishing Co., Inc., Westport, CT. (1980), at pages 424-425.

The procedure for preparing the "soft" confectionery involves known procedures. In general, the frappe component is prepared first and thereafter the syrup component is slowly added under agitation at a temperature of at least 65° C., and preferably at least 100°. The mixing of components is continued to form a uniform mixture, after which the mixture is cooled to a temperature below 80° C., at which point the flavor may be added. The mixture is further mixed for an additional period until it is ready to be removed and formed into suitable confectionery shapes.

Similar to the soft confectionery, hard confectionery may be utilized in this invention. Likewise, it may be processed and formulated by conventional means. In general, a hard confectionery has a base composed of a mixture of cane or beet sugar, polyhydric alcohols and glucose syrup, which are present in the final confectionery in amounts of between about 5% and about 99% by weight of the final composition and low moisture levels, e.g., from 0.5 to 1.5%. Such confectionery may be routinely prepared by conventional methods, such as those involving fire cookers, vacuum cookers and scraped-surface cookers also referred to as high speed atmospheric cookers.

Fire cookers involving the traditional method of making candy base, may be used. In this method the desired quantity of sugar is dissolved in water by heating in a kettle until the sugar dissolves. Corn syrup or an invert sugar is then added and cooking continued until a final temperature of 145° to 165° C. is achieved. The batch is then cooled and worked as a plastic-like mass to incorporate additives.

A high-speed atmospheric cooker uses a heat-exchange surface. Processes using it involve spreading a film of candy on a heat exchange surface, and heating the candy to 165° to 170° C. in a few minutes. The candy is then rapidly mass enabling incorporation of the additives, such as flavor, color, acidulants and medicaments. It is at this point that the inventive cooling compositions may be blended into the candy.

In vacuum cookers, the sugar and corn syrup are boiled to 125° to 132° C., vacuum applied, and additional water is boiled off without extra heating. When cooking is complete, the mass is a semi-solid, having a

plastic-like consistency. At this point, color, flavors the cooling composition and additives are mixed in the mass by routine mechanical mixing operations.

The optimum mixing required to uniformly mix the flavor, color, cooling composition and other additives during conventional manufacturing of hard confectionery is determined by the time needed to obtain a uniform distribution of the materials. Normally, mixing times of 4 to 10 minutes have been found acceptable.

Once the candy mass has been properly tempered, it may be cut into workable portions or formed into desired shapes. A general discussion of the composition and the preparation of hard confections may be found in H.A. Lieberman, *Pharmaceutical Dosage Forms: Tablets Vol 1* (1980), Marcel Dekker, Inc. at pages 339 to 469.

It should be mentioned that the apparatus useful in accordance with the present invention comprises those cooking and mixing apparatus well known in the confectionery manufacturing arts, and therefore, the selection of a specific apparatus will be apparent to the ordinary artisan.

The confectioneries useful in conjunction with the cooling composition of this invention include, but are not limited to, sugarless boiled candy, lozenges, pressed tablets, toffee and nougat, gels, minis, syrups, liquids, elixirs and the like.

The N-substituted-p-menthane carboxamide compound may be added at anytime during the preparation of the chewing gum or confectionery, since this material will not volatilize under standard processing temperatures. In contrast, menthol must be added at temperatures below its volatility point. Accordingly, these materials may be added separately to the mass being made or jointly at different times. When used together a temperature suitable to prevent the volatilization of the menthol component may be easily determined without any undue experimentation.

The present invention includes, a preferred process for preparing a confectionery composition capable of imparting breath freshening perception. The process involves preparing a soft confectionery matrix containing the components discussed above, adding menthol at a temperature below its volatility point and the N-substituted p-menthane carboxamide compound to the matrix and mixing until a uniform mass is obtained, and thereafter forming the mixture into suitable confectionery shapes.

The present invention also includes a preferred method for preparing a chewing gum composition, including both chewing gum and bubble gum formulations. The gum base is conventionally melted at temperatures that may range from about 60° to about 120° C. for a period of time sufficient to render the base molten. For example, the gum base may be heated under these conditions for a period of about thirty minutes just prior to mixing with the remaining ingredients of the gum composition. The order of addition of the remaining ingredients is not critical. A preferred procedure involves mixing the gum base with the softener until a uniform homogeneous mass is obtained, then a portion of the sweetening agent (normally one-half) is added to the heated gum base, and blending is continued until a homogeneous mass is prepared, preferably up to five minutes. Finally, the remaining sweetener and flavor oil are added, and again, blended to form a uniform composition. As one embodiment, the mixture is allowed to remain hot, and the cooling composition is added along

with the remainder of the ingredients, including the colorant, if any, and other adjuvants, and the resulting composition is then mixed for a period of time that may range as high as thirty minutes, to form a fully uniform composition. The mass is then removed from the mixer and is allowed to cool further and may thereafter be formed into various final shapes by known gum manufacturing techniques. For example, the mass may be rolled in contact with a conventional dusting medium, such as calcium carbonate, mannitol, talc and others.

The gum composition of the present invention may be prepared into all the various end forms known commercially, including slab form, stick form, cube form and center-filled form. Sugar and sugarless chewing gums are contemplated within the scope of this invention. All of the techniques associated with the preparation of the products in these forms are well known and the present method may vary somewhat depending upon the specific end product to be manufactured.

The following examples serve to provide further appreciation of the invention but are not meant in any way to restrict the effective scope of the invention. All percentages throughout the specification are by weight % of the final chewing gum composition unless otherwise indicated and wherein all percentages will total

EXAMPLE 1

Chewing gum compositions were prepared using the formulations set forth in Tables I, II, and III. The formulations were prepared by melting the gum base at a temperature of about 85 to 90° C. and then adding with mixing the lecithin followed by adding the corn syrup and $\frac{1}{2}$ of the sugar and again mixing until a homogeneous mixture was obtained, approximately 5 minutes total time. The flavor and glycerin were then added and mixed for about 2 minutes each followed by the remaining sugar which was mixed until a homogeneous mixture was obtained, about 2 minutes. The formulation was cooled to about 40 to 45° C. and the menthol and carbamate compound added and mixed into the formulation. The formulations were then cut into slab shapes.

These formulations were subjected to sensory evaluation studies to assess the perceived breath-freshening of the inventive compositions as compared to formulations containing only one of the cooling compounds. The results are recited in Tables I, II and III which results from Table I are also graphically depicted in FIG. 1. As is shown in FIG. 1, only compositions containing the cooling compositions of this invention achieve up-front and long-lasting cooling and breath freshening efforts.

TABLE I

Ingredient	COMPOSITIONS % by Weight				
	Comparative		Inventive		Comparative
	A	B	1	2	
Gum Base	21.00	21.00	21.00	21.00	21.00
Corn Syrup	16.50	16.50	16.50	16.50	16.50
44° BE					
Sugar 6x	60.60	60.60	60.60	60.60	60.60
Lecithin	0.20	0.20	0.20	0.20	0.20
Peppermint	1.1438	1.1438	1.1438	1.1438	1.1438
Flavor Oil					
Blend					
Glycerin	0.45	0.45	0.45	0.45	0.45
Menthol	0.1062	0.07965	0.0531	0.02655	—
N-ethyl-p-menthane-3-carboxamide	—	0.02655	0.0531	0.07965	0.1062
Comments:					
(a) high up-front cooling	(a) high up-front cooling	(a) high up-front cooling	(a) high up-front cooling	(a) high up-front cooling	(a) no up-front cooling
(b) cooling dropped after 2 minutes & bitterness developed	(b) cooling dropped after 2 minutes & bitterness developed	(b) cooling maintained for at least 15 to 30 minutes	(b) cooling maintained for at least 15 to 30 minutes	(b) cooling maintained for at least 15 to 30 minutes	(b) cooling gradually developed after about 6 minutes
		(c) no bitterness	(c) no bitterness		

100% of ingredients in the final composition.

TABLE II

Ingredient	COMPOSITIONS % BY WEIGHT					
	COMPARATIVE EXAMPLES					
	D	E	F	G	H	I
Gum Base	21.00	21.00	21.00	21.00	21.00	21.00
Corn Syrup	16.50	16.50	16.50	16.50	16.50	16.50
44° BE						
Sugar 6x	60.7062	60.6062	60.5062	60.6062	60.5062	60.2062
Lecithin	0.20	0.20	0.20	0.20	0.20	0.20
Peppermint	1.1438	1.1438	1.1438	1.1438	1.1438	1.1438
Flavor Oil						
Blend						
Glycerin	0.45	0.45	0.45	0.45	0.45	0.45
Menthol	—	0.10	0.20	—	—	—
N-ethyl-p-menthane-3-carboxamide	—	—	—	0.10	0.20	0.50

TABLE II-continued

Comments:	(a) upfront sweetness but no cooling effect	(a) upfront cooling and sweetness (b) after two minutes become bitter	(a) upfront cooling and sweetness (b) after two minutes become bitter	(a) upfront sweetness with little cooling after about 6 minutes (b) no harshness	(a) upfront sweetness with little cooling after about 6 minutes (b) no harshness	(a) upfront sweetness with little cooling after about 6 minutes (b) no harshness
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TABLE III

COMPOSITIONS % BY WEIGHT

Ingredients	Inventive 3	Inventive 4	Inventive 5
Gum Base	21.00	21.00	21.00
Corn Syrup	16.00	16.00	16.00
44' BE			
Sugar 6x	61.20	61.27	61.342
Spearmint flavor blend	1.3415	1.3415	1.3415
Glycerin	0.30	0.30	0.30
Color	0.025	0.025	0.025
N-ethyl-p-menthane-3-carboxamide(1)	0.21675	0.1445	0.07225

Comments:
(a) cooling composition contained 75%(1) excellent upfront and long term cooling

(b) no bitterness

(a) cooling composition contained 50%(1) good upfront and long term cooling

(b) no bitterness

(a) cooling composition contained 25%(1) good upfront cooling but poor long term cooling, bitterness after 2 minutes

components, and adding the salvage mix to the candy mass. Once homogenous, approximately 7 minutes, the mass passed through a forming apparatus and made into consumer size pieces.

The pieces were then subjected to sensory perception test according to Example 1. The results are set forth in FIG. 3.

TABLE V

	1 Grams	2 Grams	3 Grams	4 Grams
*Candy Base	53.103	52.603	53.093	52.593
Cherry Flavor	1.487	1.487	1.487	1.487
Eucalyptus Oil	0.400	0.400	0.400	0.400
**Red Color Solution	5.000	5.000	5.000	5.000
Salvage	40.000	40.000	40.000	40.000
Alcohol	0.010	0.010	0.010	0.100
Menthol	—	0.500	—	0.500
Cooling Compound 2470	—	—	0.010	0.010
	100.000	100.000	100.000	100.000

*Candy Base
Sugar - 55% Solids
Corn Syrup - 45% Solids

**Red Color Solution 2% Solution
FD&C Red #40 - 93.0
FD&C Blue #2 - 7.0
100.00

EXAMPLE 2

Chewing gum compositions were prepared using the formulations set forth in Table IV. The formulations were prepared by the procedure of Example 1.

In this example the carboxamide compounds were predissolved in ethanol as the polar solvent and then added to the chewing gum composition. The results are set forth in FIG. 2.

TABLE IV

COMPOSITIONS % BY WEIGHT

Ingredient	COMPARATIVE			INVENTIVE 6
	J	K	L	
Gum Base	21.00	21.00	21.00	21.00
Carbohydrates	77.336	77.047	77.047	77.047
Softeners	0.50	0.50	0.50	0.50
Color	0.025	0.025	0.025	0.025
Spearmint Flavor	0.85	0.85	0.85	0.85
Menthol	—	0.289	—	0.1445
Cooling Compound (Example 1)	—	—	0.289	0.1445
Solvent (Absolute Alcohol)	0.289	0.289	0.289	0.189

EXAMPLE 3

Confectionery compositions were prepared using the formulations set forth in Table V. The formulations were prepared by melting the candy base to a plastic mass, remelting the salvage, which is previously prepared candy, and mixing into the salvage the remaining

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications are intended to be included within the scope of the following claims.

We claim:

1. A chewing gum composition capable of providing long-lasting, breath freshening perception without bitterness comprising a gum base, a sweetener and a cooling composition comprising menthol and an N-substituted-p-menthane carboxamide of the formula:



wherein R_1 , when taken separately, is selected from the group consisting of hydrogen, and an aliphatic radical containing up to 25 carbon atoms;

R_2 , when taken separately is selected from the group consisting of a hydroxy radical, and an aliphatic radical containing up to 25 carbon atoms, with the proviso that when R_1 is hydrogen R_2 may also be an aryl radical of up to 10 carbon atoms and se-

lected from substituted phenyl, phenalkyl, naphthyl and substituted naphthyl, and pyridyl; and R_1 and R_2 when taken together, represent a cyclic or heterocyclic group of up to 25 carbon atoms.

2. The chewing gum composition of claim 1 wherein the N-substituted-p-menthane carboxamide is N-ethyl-p-menthane-3-carboxamide.

3. The chewing gum composition of claim 1 wherein the menthol and N-substituted-p-menthane carboxamide are used in amounts of about 30 to about 95% by weight N-substituted p-menthane carboxamide and about 5 to about 7% by weight menthol, all weights being by weight of the cooling composition.

4. The chewing gum composition of claim 3 wherein the menthol is used in amounts of about 20 to about 60% by weight of the cooling composition.

5. The chewing gum composition of claim 3 wherein the N-substituted-p-menthane carboxamide is used in amounts of about 40 to about 80% by weight of the cooling compositions.

6. The chewing gum composition of claim 1 wherein the cooling composition is present in the chewing gum composition in the amount of about 0.01 to about 2% by weight of the total chewing gum composition.

7. The chewing gum composition of claim 1 wherein the gum base is selected from the group consisting of natural or synthetic elastomers.

8. The chewing gum composition of claim 1 wherein the sweetener is a natural or synthetic compound.

9. The chewing gum composition of claim 1 containing one or more of the additional components selected from the group consisting of fillers, plasticizers, softeners, coloring agents, flavors, and mixtures thereof.

10. The chewing gum composition of claim 1 wherein the sweetener is selected from the group consisting of water-soluble sweetening agents, water-soluble artificial sweeteners, dipeptide based sweeteners and mixtures thereof.

11. The chewing gum composition of claim 1 wherein the sweetener is selected from the group consisting of liquid sweeteners, particulate sweeteners and mixtures thereof.

12. A confectionery composition capable of providing long-lasting, breath freshening perception without bitterness comprising a confectionery matrix and a cooling composition comprising menthol and an N-substituted-p-menthane carboxamide of the formula:



wherein R_1 when taken separately, is selected from the group consisting of hydrogen, and an aliphatic radical containing up to 25 carbon atoms;

R_2 when taken separately is selected from the group consisting of a hydroxy radical, and an aliphatic radical containing up to 25 carbon atoms, with the proviso that when R_1 is hydrogen R_2 may also be an aryl radical of up to 10 carbon atoms and selected from substituted phenyl, phenalkyl, naphthyl and substituted naphthyl, and pyridyl; and

R_1 and R_2 when taken together, represent a cyclic or heterocyclic group of up to 25 carbon atoms.

13. The confectionery composition of claim 12 wherein the N-substituted p-menthane carboxamide is N-ethyl-p-menthane-3-carboxamide.

14. The confectionery composition of claim 12 wherein the menthol and N-substituted-p-menthane carboxamide are used in amounts of about 30 to about 95% by weight N-substituted-p-menthane carboxamide and about 5 to about 70% by weight menthol, all weights being by weight of the cooling composition.

15. The confectionery composition of claim 14 wherein the menthol is used in amounts of about 20 to about 60% by weight of the cooling composition.

16. The confectionery composition of claim 14 wherein the N-substituted-p-menthane carboxamide is used in amounts of about 40 to about 80% by weight of the cooling compositions.

17. The confectionery composition of claim 12 wherein the cooling composition is present in the confectionery composition in an amount of about 0.01 to about 2% by weight of the total confectionery composition.

18. The confectionery composition of claim 12 wherein the composition additionally contains a sweetener which selected from the group consisting of water-soluble sweetening agents, water-soluble artificial sweeteners, dipeptide based sweeteners and mixtures thereof.

19. A process of preparing a chewing gum composition capable of imparting breath freshening perception which comprises:

- admixing a chewing gum base at a temperature of about 70° C. to about 120° C. with a softener to obtain a homogenous pliable mixture;
- continuing to mix while adding a sweetening agent;
- adding menthol and a N-substituted-p-menthane carboxamide compound and the remaining chewing gum ingredients and continue mixing until a uniform mass is obtained; and
- thereafter forming the mixture into suitable chewing gum shapes.

20. The process of claim 19 wherein the N-substituted-p-menthane carboxamide compound is added in the form of a particulate solid.

21. The process of claim 19 wherein the N-substituted-p-menthane carboxamide compound is dissolved in a polar solvent and then added to the mixture.

22. The process of claim 19 wherein the N-substituted-p-menthane carboxamide compound is mixed with a flavor oil and then added to the mixture.

23. The process of claim 19 wherein the N-substituted-p-menthane carboxamide compound is encapsulated and then added to the mixture.

24. The process of claim 19 wherein the menthol and N-substituted-p-menthane carboxamide compound is added separately and admixed in the chewing gum base.

25. A process for preparing a confectionery composition capable of imparting breath freshening perception which comprises:

- preparing a soft confectionery matrix;
- adding menthol and a N-substituted-p-menthane carboxamide compound to the matrix and mixing until a uniform mass is obtained; and
- thereafter forming the mixture into suitable confectionery shapes.

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26. The process of claim 25 wherein the N-substituted-p-menthane carboxamide compound is added in the form of a particulate solid.

27. The process of claim 25 wherein the N-substituted-p-menthane carboxamide compound is dissolved in a polar solvent and then added to the mixture.

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28. The process of claim 25 wherein the N-substituted-p-menthane carboxamide compound is mixed with a flavor oil and then added to the mixture.

29. The process of claim 25 wherein the N-substituted-p-menthane carboxamide compound is encapsulated and then added to the mixture.

30. The process of claim 25 wherein the menthol and N-substituted-p-menthane carboxamide compound is added separately and admixed in the confectionery matrix.

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EXHIBIT E

United States Patent [19]

Oppenheimer et al.

[11] Patent Number: 4,980,169

[45] Date of Patent: Dec. 25, 1990

[54] FLAVOR ENHANCING AND INCREASING
EFFICACY OF COUGH DROPS

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424/440; 424/441; 424/465; 514/974

[58] Field of Search 424/440, 441, 439, 195.1,
424/465; 514/974

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[57] ABSTRACT

A novel confection containing a volatile oil for dissolving in the oral cavity is disclosed. The confection contains a sensorially undetectable amount of a volatile oil modifying agent which enhances the flavor of the volatile oil as well as ameliorates the perception of unpleasant organoleptic sensations such as bitterness initiated by the volatile oil being released in the oral cavity. In a preferred embodiment, the modifying agent is capsaicum and most preferably, the oleoresin form of capsaicum.

10 Claims, No Drawings

FLAVOR ENHANCING AND INCREASING EFFICACY OF COUGH DROPS

BACKGROUND OF THE INVENTION

The present invention relates to improved formulations for confections which are intended to reside in the oral cavity for a period of time while being consumed. In particular, the present invention provides, among other things, medicinal tablets with enhanced flavored delivery as the confection dissolves in the oral cavity.

Confections, especially medicinal tablets which deliver active ingredients in the oral cavity, are well known in the art and may be divided into various classes based upon their composition or intended effect. Examples include lozenges, compressed tablets and other medicinal tablets. The confections may have breath fresheners, breath deodorants, cough suppressants, nasal decongestants and the like.

Over the years, considerable effort has been directed to improving sensory perception in the oral cavity of the volatile oils contained in confections. Volatile oils or essential oils are derived from the leaves, stems or flowers of numerous plants and usually carry the savory or odorous principles of the plant which is obtained by distillation, expression or extraction. Volatile oils are known for their variable odors and distinctive tastes. The odors of volatile oils are modified by exposure to air, and the tastes of the volatile oils are quite distinctive. Some are sweet, while others can be mild, pungent, hot, acrid, caustic or burning in taste. In addition, some volatile oils can be made synthetically.

Enhancing the impact of the volatile oils in the oral cavity increases the benefit of the confection by ameliorating perceived bitterness, pungency, or other undesirable organoleptic sensations.

Menthol is isolated principally from the oil of *Mentha arvensis*. In its commercial form, menthol is present as crystals obtained from a process involving cooling of the above mentioned oil. Fractional distillation of peppermint oil which usually contains from about 50% to about 65% menthol provides another important source of menthol. In addition, menthol can be provided synthetically.

The use of menthol, for example, for its medicinal effect is known in the art. Menthol's cooling effect to the mouth is useful to relieve local irritations in the throat and mouth.

Eucalyptus is another essential oil often combined with other essential oils such as menthol in confection formulations to impart medicinal effect. In particular, eucalyptus is believed to exhibit an expectorant action. The combination of the essential oils of menthol and eucalyptus, in a formulation capable of dissolving in the oral cavity provide a useful medicinal preparation in treatment of coughs and minor mouth, throat, and upper respiratory irritations.

Confections which include such medicinal formulations, e.g., cough drops, lozenges, etc., however, suffer from several shortcomings. For example, bitterness is often perceived due to the high potency of the essential oils which contain menthol. The bitterness of the menthol released in the oral cavity, therefore, provides an unpleasant organoleptic experience to the user, thus reducing the likelihood of continued treatment with the lozenge or tablet. In addition, prior art preparations containing menthol suffer from reduced efficacy due to the erratic release of the menthol contained within the

confection. Consequently, the cooling effect of menthol has often been attenuated. These problems, therefore, tend to detract from the acceptance of menthol-containing products as adjuncts in cough and cold therapy.

Other confectionery products, which may contain menthol or other flavorants derived from essential oils, such as spearmint, and/or peppermint, have also been known to produce bitterness while residing in the oral cavity.

While not an essential oil, the fruits of various species of capsicum are often added to food preparations to impart a pungent taste. Capsicum generally refers to various types of pepper of varying degrees of pungency. Capsicum oleoresin is an extract of fruits from various capsicum species and consists of a resinous matter and a liquid phase. The capsicum oleoresin is extremely pungent. For example, a dilution of one part of capsicum oleoresin in five million parts of 9% sugar water at 10° C. produces a distinct burning effect in the throat and posterior region of the oral cavity. The capsicum oleoresin, with its characteristic peppery odor and extremely high bite, provides a useful source of aromas and is useful as an additive in various condiments, sauces and other foods. The traditional use of capsicum, therefore, is to provide a peppery heat sensation or spicy bite to foods or other confectionery items.

In the past, capsicum has generally been limited to those uses which rely on its peppery hot sensation or bite properties. U.S. Pat. No. 4,198,393 to Yoshida et al., discloses using cyclic acetals of 2-methyl-2-pentanol with capsicum and volatile oils, to provide flavor compounds that demonstrate a primary flavor taste and a purported ethereal effect.

U.S. Pat. No. 4,420,472 to Boden, et al. discloses the use of phenyl methyl carbonate to enhance the flavor and aroma of chewing gums, toothpaste and medicinal products containing various flavor adjuncts including capsicum and other black pepper oleoresins as well as numerous volatile oils.

U.S. Pat. No. 4,197,328 to Sprecker, et al. discloses the use of oxabicyclooctanes to augment or enhance a variety of flavors and fragrances in various consumable materials. Similar to Yoshida, et al., capsicum and various volatile oils are among possible co-ingredients used as a flavor adjuncts enhanced by the oxabicyclooctanes.

U.S. Pat. No. 4,423,030 to Hayes, et al. discloses dental creams or mouthwashes having "two-tone flavors" provided by an essential oil component comprising about 0.01-5% by weight and a water-insoluble oleoresin component comprising about 0.001-0.1% by weight. Capsicum varieties are included among the oleoresins and are relied upon to provide a sensation of pungency different from that provided by the essential oil.

It is, therefore, an object of the present invention to provide an improved confection having essential oils with reduced perception of bitterness upon the release of the essential oil into the oral cavity.

Another object of the present invention is to provide a natural food additive which enhances the flavor and organoleptic sensation of essential oils in the oral cavity.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided an improved confection composition containing a volatile oil which enhances the organoleptic per-

ception of the volatile oil as the confection dissolves in the oral cavity. The new composition includes a volatile oil-modifying agent which ameliorates perceived undesirable organoleptic sensations such as bitterness. The volatile oil-modifying agent is present in an amount which is sensorially undetected in the oral cavity so that the desired aroma and flavor of the volatile oil is perceived without detecting the modifying agent.

In a preferred embodiment, the volatile oil modifying agent is capsaicin. In a most preferred embodiment the capsaicin is present in the oleoresin form. The modifying agent may be present in an amount of from about 1 to about 150 parts per million (ppm) of the confection by weight, preferably in an amount of from about 5 to about 80 ppm, and most preferably from about 10 to about 50 ppm.

The flavor and aroma imparting properties of the confection can be provided by volatile oils selected from both natural and synthetic sources. Typically, the volatile oil is present in an amount of from about 0.05 to about 1.0% by weight of the confection. The amount of volatile oil varies, however, in accordance with the desired flavor and aroma of the confection product. In addition, the confection may contain a blend of volatile oils and other sweeteners to provide the desired flavor in the oral cavity. Examples of suitable volatile oils include spearmint, eucalyptus, peppermint, menthol and wintergreen (methyl salicylate) oils. Additionally, the confections of the present invention can also include sweeteners such as sugar, sugar alcohols, and artificial sweeteners.

In one embodiment, there is provided a confection containing a blend of eucalyptus and 1-menthol and the modifying agent to ameliorate the perceived bitterness of the volatile oil combination. The above-mentioned combination is useful in cough and cold therapy as well as having a decongestant effect in the nasal cavity.

Also provided is a method of enhancing sensory perception of a volatile oil in the oral cavity. The volatile oil is included in a confection designed to dissolve in the oral cavity. The confection also contains an amount of a volatile oil-modifying agent to modify the sensory perception of the volatile oil released in the oral cavity. The modifying agent is undetected as a separate agent but sensorially organoleptic sensations of the oils, such as bitterness, are substantially eliminated.

Unlike the prior art approaches to flavor modification, the use of capsaicin in this invention to enhance the flavor delivery of essential oils is achieved without detection of the capsaicin. Further, the prior art use of capsaicin is largely limited to providing pungent flavor. Indeed, the flavor enhancing qualities of capsaicin on essential oils has heretofore been unrealized. The prior art also does not disclose or suggest the ability of capsaicin to reduce the bitterness of essential oils as they are released from compressed tablets into the oral cavity.

As a result of the present invention, an improved confectionery product can be provided which has enhanced flavor properties as well as substantial reductions in unpleasant organoleptic sensations such as bitterness upon the release of the volatile oil from the confection in the oral cavity.

For a better understanding of the present invention, together with other and further objects, reference is made to the following description and its scope will be pointed out in the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

It has now been surprisingly found that the disadvantages associated with confections containing a volatile oil which imparts a bitter taste upon release in the oral cavity can be overcome by using the novel method and composition of the present invention. The novel confection contains a volatile oil and a modifying agent, preferably capsaicin, present in an amount which is undetected as a separate ingredient in the oral cavity, but nevertheless has the ability to modify sensory perception of the volatile oil.

In a preferred embodiment, the confection contains both menthol and eucalyptus as the volatile oil component and the volatile oil modifying agent is capsaicin oleoresin present in an amount of from about 1 to about 30 ppm. In this embodiment, the confection confers medicinal benefits by providing active ingredients which relieve irritations of the nasopharyngeal region caused by coughing as well as providing a decongestant effect in the nasal cavity by vapor action released from the confection.

In an alternative embodiment, there is also provided a confection which contains non-medicinal volatile oils which impart a flavor sensation in the oral cavity upon dissolving in the oral cavity. In this embodiment, the confection also contains a volatile oil-modifying agent which enhances the impact of the volatile oil released from the confection in the oral cavity. The volatile oil-modifying agent reduces the perceived bitterness, pungency, or other undesirable organoleptic sensation.

The preparation of confectionery formulations is historically well known and has changed little through the years. Confectionery items have been classified as either "hard" confectionery or "soft" confectionery. The volatile oil-modifying agent of the present invention can be incorporated by admixing the modifying agent into conventional hard and soft confections.

Hard confectionery may be processed and formulated by conventional means. In general, a hard confectionery has a base composed of a mixture of sugar and other carbohydrate bulking agents kept in an amorphous or glassy condition. This form is considered a solid syrup of sugars generally having from about 0.5% to about 1.5% moisture. Such materials normally contain up to about 92% corn syrup, up to about 55% sugar and from about 0.1% to about 5% water, by weight of the final composition. The syrup component is generally prepared from corn syrups high in fructose, but may include other materials. Further ingredients such as flavorings, sweeteners, acidulants, colorants and so forth may also be added.

Such confectionery may be routinely prepared by conventional methods such as those involving fire cookers, vacuum cookers, and scraped-surface cookers also referred to as high speed atmospheric cookers.

Fire cookers involve the traditional method of making a candy base. In this method, the desired quantity of carbohydrate bulking agent is dissolved in water by heating the agent in a kettle until the bulking agent dissolves. Additional bulking agent may then be added and cooking continued until a final temperature of 145° to 156° C. is achieved. The batch is then cooled and worked as a plastic-like mass to incorporate additives such as flavors, colorants and the like.

A high-speed atmospheric cooker uses a heat-exchanger surface which involves spreading a film of

candy on a heat exchange surface, the candy is heated to 165° to 170° C. in a few minutes. The candy is then rapidly cooled to 100° to 120° C. and worked as a plastic-like mass enabling incorporation of the additives, such as flavors, colorants and the like.

In vacuum cookers, the carbohydrate bulking agent is boiled to 125° to 132° C., vacuum is applied and additional water is boiled off without extra heating. When cooking is complete, the mass is a semi-solid and has a plastic-like consistency. At this point, flavors, colorants, and other additives are admixed in the mass by routine mechanical mixing operations.

The optimum mixing required to uniformly mix the flavors, colorants and other additives during conventional manufacturing of hard confectionery is determined by the time needed to obtain a uniform distribution of the materials. Normally, mixing times of from 4 to 10 minutes have been found to be acceptable.

Once the candy mass has been properly tempered, it may be cut into workable portions or formed into desired shapes. A variety of forming techniques may be utilized depending upon the shape and size of the final product desired. A general discussion of the composition and preparation of hard confections may be found in H. A. Lieberman, *Pharmaceutical Dosage Forms: Tablets*, Volume 1 (1980), Marcel Dekker, Inc., New York, N.Y., at pages 339 to 469, which disclosure is incorporated herein by reference.

The apparatus useful in accordance with the present invention comprises cooking and mixing apparatus well known in the confectionery manufacturing arts, and selection of the specific apparatus will be apparent to the artisan.

Similar to hard confectionery, soft confectionery may be utilized in this invention. The preparation of soft confections, such as nougat, involves conventional methods, such as the combination of two primary components, namely (1) a high boiling syrup such as corn syrup, hydrogenated starch hydrolysate or the like, and (2) a relatively light textured frappe, generally prepared from egg albumin, gelatin, vegetable proteins, such as soy derived compounds, sugarless milk derived compounds such as milk proteins, and mixtures thereof. The frappe is generally relatively light, and may, for example, range in density from about 0.5 to about 0.7 grams/cc.

The high boiling syrup, or "bob syrup" of the soft confectionery is relatively viscous and has a higher density than the frappe component, and frequently contains a substantial amount of carbohydrate bulking agent such as a hydrogenated starch hydrolysate. Conventionally, the final nougat composition is prepared by the addition of the "bob syrup" to the frappe under agitation, to form the basic nougat mixture. Further ingredients such as flavoring, additional carbohydrate bulking agent, colorants, preservatives, medicaments, mixtures thereof and the like may be added thereafter also under agitation. A general discussion of the composition and preparation of nougat confections may be found in B. W. Minifie, *Chocolate, Cocoa and Confectionery: Science and Technology*, 2nd edition, AVI Publishing Co., Inc., Westport, Conn. (1980), at pages 424-425, which disclosure is incorporated herein by reference.

The procedure for preparing the soft confectionery involves known procedures. In general, the frappe component is prepared first and thereafter the syrup component is slowing added under agitation at a temperature

of at least about 65° C., and preferably at least about 100° C. The mixture of components is continued to be mixed to form a uniform mixture, after which the mixture is cooled to a temperature below 80°C, at which point, the flavor may be added. The mixture is further mixed for an additional period until it is ready to be removed and formed into suitable confectionery shapes.

The flavoring components of the confection are flavors having an associated bitter taste or other unpleasant after taste. These flavoring components may be chosen from natural and synthetic flavoring liquids such as volatile oils, synthetic flavor oils, flavoring aromatic and oils, liquids, oleoresins or extracts derived from plants, leaves, flowers, fruits, stems and combinations thereof. Non-limiting representative examples of volatile oils include spearmint oil, cinnamon oil, oil of wintergreen (methyl salicylate), peppermint oil, menthol, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, cedar leaf oil, oil of nutmeg, allspice oil, oil of sage, mace extract, oil of bitter almonds, and cassia oil. In addition, the confection may also contain artificial, natural or synthetic flavors including fruit flavors such as vanilla, and citrus oils including lemon, orange, grape, lime and grapefruit and fruit essences including apple, pear, peach, grape, strawberry, raspberry, cherry, plum, pineapple, apricot and so forth.

Other useful flavorings include aldehydes and esters such as benzaldehyde (cherry, almond), citral, i.e., alpha-citral (lemon, lime), neral, i.e., beta-citral (lemon, lime), decanal (orange, lemon), aldehyde C-8 (citrus fruits), aldehyde C-9 (citrus fruits), aldehyde C-12 (citrus fruits), tolyl aldehyde (cherry, almond), 2,6-dimethyl-octanal (green fruit), and 2-dodecenal (citrus, mandarin), mixtures thereof and the like.

In the instance where sweeteners are utilized, the present invention contemplates the inclusion of those sweeteners well known in the art, including both natural and artificial sweeteners. The sweeteners may be chosen from the following non-limiting list: sugars such as sucrose, glucose (corn syrup), dextrose, invert sugar, fructose, and mixtures thereof, saccharin and its various salts such as the sodium or calcium salt; cyclamic acid and its various salts such as the sodium salt; the dipeptide sweeteners such as aspartame, dihydrochalcone compounds, glycyrrhizin; *Stevia Rebaudiana* (Stevioside); chloro derivatives of sucrose; dihydroflavinol; hydroxyguaiaicol esters; L-amino dicarboxylic acid gem-diamines; L-amino dicarboxylic acid aminoalkenoic acid ester amides; and sugar alcohols such as sorbitol, sorbitol syrup, mannitol, xylitol, and the like. Also contemplated as an additional sweetener is the non-fermentable sugar substitute (hydrogenated starch hydrolysate) which is described in U.S. Reissue Pat. No. 26,959. Also contemplated is the synthetic sweetener 3,6-dihydro-6-methyl-1-1,2,3-oxathiazin-4-one-2,2-dioxide, particularly the potassium (acesulfame-K), sodium and calcium salts thereof as described in German Patent No. 2,001,017.7.

In addition, the confection may also contain suitable auxiliary flavorings including both natural and artificial flavors, and mints such as peppermint, artificial vanilla, cinnamon, various fruit flavors, both individual and mixed. Such flavorings are generally utilized in amounts that will vary depending upon the particular confection and volatile oil selected.

The confection may also include a colorant. The colorants may be selected from any of the numerous dyes suitable for food, drug and cosmetic applications,

and known as FD&C dyes and the like. The materials acceptable for the foregoing spectrum of use are preferably water-soluble. Illustrative examples include indigo dye, known as FD&C Blue No. 2, which is the disodium salt of 5,5'-indigotin-3,3'-disulfonic acid. Similarly, the dye known as FD&C Green No. 1 comprises a triphenylmethane dye and is the monosodium salt of 4-[4-(N-ethyl-N-sulfonylbenzylamino) diphenylmethyl]-1-(N-ethyl-N-sulfonylbenzyl)-2,5-cyclohexadienimine]. A full recitation of all FD&C and D&C dyes and their corresponding chemical structures may be found in the *Kirk-Othmer Encyclopedia of Chemical Technology*, in Volume 5, pages 857-884, which is incorporated herein by reference.

In the case of a hard boiled cough drop-type confection, the volatile oil component is present in an amount from about 0.05 to about 1.0% by weight depending upon the confection, the volatile oil selected, and additional flavorings or sweeteners if added.

The volatile oil-modifying agent is preferably capsicum oleoresin. To effect the novel volatile oil enhancing properties of the present invention the modifying agent is present in an amount of from about 1 to about 150 ppm of the confection. The preferred range of capsicum is from about 5 to about 80 ppm, while the most preferred range is from about 9 to about 50 ppm of the confection.

The capsicum is available from *Capsicum minimum*, *Capsicum frutescens*, *Capsicum annuum*, and similar varieties. Commercially, the fruits of capsicum are referred to as chilies or as peppers. These fruits are known for their extreme potency of bite, pungency and characteristic odor.

Capsicum oleoresin is a dark red or orange-red liquid obtained by solvent extraction of a dried ripe fruit of *Capsicum frutescens* or *Capsicum annuum*. The capsicum oleoresin has a characteristic odor and extremely high bite. For example, usually within the range of 250,000 to 1,000,000 Scoville heat units. Capsicum oleoresin also has a distinct burning effect in the throat and posterior portion of the mouth.

Although capsicum and capsicum oleoresin are considered to be potent sources of peppery or pungent flavor, it has now been found that they enhance flavor delivery of volatile oils when present in amounts ranging from about 1 ppm to about 30 ppm. Key, however, to the present invention is the discovery that when capsicum is present in confections in the amounts set forth above, the capsicum is undetectable in the oral cavity yet at the same time provides enhanced flavor delivery of the companion volatile oil.

With respect to confectionery compressed tablet formulations, such will contain a tablet granulation base and various additives such as sweeteners and flavors. The tablet granulation base employed will vary depending upon factors such as the type of base used, friability desired and other components used to make the final product. The confectionery compressed tablet made in accordance with the present invention, however, contains a volatile oil and a volatile oil-modifying agent in amounts similar to the above cough drop example. These confections generally contain sugars in amounts up to 95% by weight of the composition. The confectionery compressed tablet may additionally include tablet excipients such as binders or lubricants, as well as flavoring agents and coloring agents.

The variations that one may practice with regard to these confections are wide ranging and within the abil-

ity of those skilled in the art particularly with regard to the use of additional composition fillers, flavoring adjuncts, the use of coloring agents, etc.

As previously mentioned, the volatile oil component of the confection may include menthol. In particular, the most important commercial source is l-menthol. Commercial l-menthol is isolated principally from the oil of *Mentha arvensis*. The process involves cooling of the oil and purifying the crystals formed. Menthol possesses a distinct peppermint flavor and gives the impression of cooling the mouth and skin.

L-menthol and eucalyptus oil may be combined to provide the volatile oil component of the confection. When so combined, the menthol-eucalyptus is useful as an adjunct to coughing cold therapy. Eucalyptus is believed to impart decongestant type activity while menthol provides soothing of the mouth and throat areas. When the volatile oil modifying agent capsicum is combined with the above volatile oil combination menthol-eucalyptus, it has been found that the modifying agent substantially ameliorates the unpleasant organoleptic experience often detected when confectionery formulations containing the above ingredients dissolve in the oral cavity.

Tests were conducted by using the confection of the present invention to compare it with confection products not containing a volatile oil-modifying agent, and it was found that not only were the flavor enhancing properties of the capsicum evident but also that such inventive confections were undetectable for peppery taste.

EXAMPLES

The following examples serve to provide further appreciation of the invention but are not meant in any way to restrict the effective scope of the invention.

EXAMPLE 1

A control hard boiled cough drop was prepared using the following formulation.

INGREDIENT	PERCENT BY WEIGHT	
	A	B
Sugar (fine granulated)	54.7830	54.8185
Corn syrup 43 Baume	44.8210	44.8315
Citric acid	0.2160	—
l-menthol	0.1000	0.1733
Eucalyptus oil	0.0800	0.1567
Capsicum Oleoresin	—	—
	100.000	100.000

Additionally, the inventive confections with the volatile oil modifying agent capsicum oleoresin were prepared in accordance with the following formula.

INGREDIENT	PERCENT BY WEIGHT	
	SAMPLE C	SAMPLE D
Sugar-fine granulated	54.7820	54.8190
Corn syrup 43 Baume	44.8210	44.8310
Citric acid	0.2160	—
l-menthol	0.1000	0.1711
Eucalyptus oil	0.0800	0.1546
Capsicum Oleoresin	0.0010	0.0043
	100.0000	100.0000

Each of the above were then subject to testing for sensory evaluation. The results are set forth below.

EXPERT PANEL TESTING

SPECIMEN	FLAVOR	BITTERNESS
Control A	Moderate	Detectable
Control B	Strong	Quite Noticeable
Sample C	Excellent	Slightly Perceivable
Sample D	Excellent	Slightly Perceivable

Control Samples A and B were described as having a harsh flavor with a strong menthol presence and associated bitterness. Inventive Sample C and D, on the other hand, were described as having significantly less bitterness and an organoleptically pleasing menthol-eucalyptus flavor with more enhanced menthol cooling than the Controls.

As can be seen, the confection products of the present invention provided favorable results when compared to the control samples. Whereas in the past, confections containing menthol and/or eucalyptus often provided undesired organoleptic sensations such as bitterness, the inventive compositions clearly demonstrate decreased bitterness upon the release of the essential oil(s) into the oral cavity. In addition, organoleptic sensations in the oral cavity are enhanced with the product of the present invention.

Thus, while there has been described what are presently believed to be the preferred embodiment of the present invention, and further embodiments will be realized by those skilled in the art, and it is intended to claim all such embodiments as come within the true scope of the invention.

What is claimed is:

1. A confection for dissolving in the oral cavity comprising:

- (a) a volatile oil; and
- (b) a volatile oil-modifying agent in an amount which is sensorially undetected in the oral cavity but sufficient to modify sensory perception of said volatile oil as it is released in the oral cavity.

2. The confection of claim 1 wherein said capsaicin oleoresin is present in an amount of from about 5 to about 80 ppm in said confection.

3. The confection of claim 2 wherein said capsaicin oleoresin is present in an amount of from about 9 to about 50 ppm in said confection tablet.

4. The confection of claim 1 wherein said volatile oils are selected from the group consisting of menthol, l-menthol, anise, caraway, cinnamon, clove, coriander, eucalyptus, fennel, lavender, lemon, orange, orange flower, peppermint, pine needle, spearmint, and mixtures thereof.

5. The confection of claim 1 wherein said volatile oil is present in an amount of from about 0.05 to about 1.0 percent by weight of said confection.

6. The confection of claim 5 wherein said volatile oil is present in an amount of from about 0.06 to about 0.75 percent by weight of said confection.

7. The confection of claim 6 wherein said volatile oil is present in an amount of from about 0.15 to about 0.50 percent by weight of said confection.

8. A method of enhancing sensory perception of volatile oils in the oral cavity comprising:

providing a volatile oil-modifying agent in an amount which is sensorially undetected in the oral cavity but sufficient to modify the sensory perception of said volatile oil as it is released in the oral cavity.

9. The method of claim 8 wherein said volatile oils are selected from the group consisting of menthol, l-menthol, anise, caraway, cinnamon, clove, coriander, eucalyptus, fennel, lavender, lemon, orange, orange flower, peppermint, pine needle, spearmint, and mixtures thereof.

10. A medicinal tablet for dissolving in the oral cavity comprising:

- (a) menthol; and
- (b) a menthol modifying agent in an amount which is sensorially undetected in the oral cavity but sufficient to modify sensory perception of said menthol as it is released from said medicinal tablet in the oral cavity.

* * * * *

EXHIBIT F

[54] LOW MENTHOL MINT PLANT *MENTHA SPICATA* L. 'EROSPICATA'

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[73] Assignee: Aromatics, Inc., Salem, Oreg.

[21] Appl. No.: 968,031

[22] Filed: Oct. 27, 1992

[51] Int. Cl.⁵ A01H 5/00

[52] U.S. Cl. Pft./100

[58] Field of Search Pft. 100

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Assistant Examiner—Erich E. Veitenheimer
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[57] ABSTRACT

A novel *Mentha spicata* mint plant characterized by its resistance to verticillium wilt and mint rust, and an essential oil with a relatively low l-menthol content and high menthone content. The oil, which has at most only minor amounts of piperitone and l-carvone, is characterized by peppermint-like taste and a hot odor.

2 Drawing Sheets

1

The present invention relates to a new and distinct variety of mint plant of the species botanically known as *Mentha spicata*. I have named by new variety "Erospicata."

I discovered my new variety as a chance seedling from a self pollination of a parent plant *M. spicata* L. var *crispata* Schrad. The seedling was grown in a cultivated area of my nursery in Oregon. My attention was first directed to the new plant because of its hot smell. I further observed disease resistance of this plant to verticillium wilt and mint rust. Analysis of the oil of this plant showed that it was quite unusual and distinct from other *M. spicata*.

Close observations of the new seedling and continued observations of progeny thereof subsequently asexually propagated under my direction on land near Corvallis, Oreg., by rooting cuttings, has confirmed that the unique characteristics of my new variety are a result of a seedling variation. I am therefore convinced that my new mint plant represents a new and improved variety of *Mentha spicata*, as particularly evidenced by the following unique combination of characteristics, which have proven firmly fixed, or outstanding, and which distinguish it from all other varieties of this species.

1. Low l-menthol content and high menthone content as compared to the oil of its *Mentha spicata* parent.

2. Only minor amounts of piperitone and l-carvone in the oil produced by the plant.

3. Disease resistance to verticillium wilt and mint rust.

4. A hot odor as opposed to the cool odor of its parent.

The accompanying photographs depict the color of my new variety of mint plant as nearly true as is reasonably possible to make the same in a color illustration of this character.

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FIG. 1 is a color photograph of a plant of the present invention.

FIG. 2 is an enlarged photograph showing a leaf of the plant of FIG. 1.

One of the primary distinguishing features of my new mint plant over other mint plants of this species is that it has a characteristic peppermint taste and smell, yet its oil contains much lower levels of menthol and much higher levels of menthone. The *M. spicata* plant of the present invention produces an essential oil with an l-menthol content of less than about 5% by weight, a piperitone content of less than about 2%, and has more than about 50% l-menthone, and is substantially free of l-carvone. The essential oil, preferably comprises less than about 1% by weight l-menthol, less than about 1% piperitone, and at least 50% l-menthone. In particularly preferred embodiments, the essential oil comprises 55-60% l-menthone, less than about 1% l-menthol, less than about 1% piperitone, and is substantially free of l-carvone, menthofuran, menthyl acetate, and trans-sabinene hydrate. The oil contains sufficient amounts of menthone that it has the organoleptic properties of peppermint oil.

The low menthol content of the essential oil is important because menthol is an alcohol that irritates nasal, oral and gastrointestinal epithelium. Hence only very small amounts of conventional peppermint oil can be added to ingestible products such as candy. The plant of the present invention has retained sufficient menthone content to provide a "hot" peppermint taste and odor, but menthol is substantially absent from the oil. The absence of this alcohol helps avoid nasal and gastrointestinal irritation, while the menthone provides peppermint-like organoleptic properties. My new mint plant also expresses an oil that is low in carvone and piperitone content. The substantial absence of carvone and

piperitone is important because these substances provide a taste that is organoleptically undesirable in peppermint oil. Carvone provides a spearmint taste, while piperitone imparts a bitter taste.

The mint plant of the present invention has an essential oil that, when analyzed by gas chromatographic analysis, includes the following weight percentages of menthone, carvone, menthol and piperitone:

l-menthone	>40
d-isomenthone	>15
carvone	<01
l-menthol	<1
piperitone	<1

An example of the plant of the present invention is deposited with the U.S.D.A. National Clonal Germplasm Repository in Corvallis, Oreg., under accession number MEN625.

Strain 86-183

The Erospecta variety is referred to herein as strain 86-183. Strain 86-183 relates to a new variety of mint plant originating at St. S. station from the self-pollination of a clonal strain of *M. spicata* L. The parent plant of strain 86-183 is a wild spearmint obtained from the National Germplasm Repository in Corvallis, Oreg., under accession no. MEN57. This parent strain was originally numbered 71-62 by the originator, Dr. J. M. Murray, of the A. M. Todd Co. in Kalamazoo, Mich. Clone 71-62 was called *M. crispata* L. or *M. spicata* L. var *crispata* Schrad. It is a fertile allotetraploid plant with a chromosome number of 48. The 71-62 plant is resistant to verticillium wilt (*Verticillium albo-atrum*) and is believed to be immune to mint rust (*Puccinia menthae*). The 71-62 strain is glabrous and yields an essential oil containing about 70% of the ketone carvone, and less than 1% menthol, but it also has less than 1% menthone. It therefore lacks the odor or taste of peppermint that would be provided by menthol or menthone, yet has the spearmint odor and taste provided by carvone. The leaves are crisp or ruffled, hence the original name crisp. It has been shown that carvone-odored *M. crispata* has a genotype that segregates 16 spearmint in a 12 high carvone; 3 high menthone; 1 high piperitone ratio in the S_1 progeny. A major consideration in the use of the wild spearmint parent, *M. crispata* (71-62), was its excellent resistance to verticillium wilt and leaf rust.

General Objectives of this Breeding Program

The broad objectives of this breeding program were to try bring together in one plant the characteristics deemed necessary for a successful commercial essential oil crop. The two most important traits were disease resistance to wilt and rust, and an essential oil high in the major peppermint flavor components and low in undesirable compounds. High vigor and aggressive stolon development were also considered desirable traits. The parent plant (71-62) met the criteria of disease resistance and vigor.

Breeding Program History

The parent plant (71-62) was self pollinated in the summer, and seeds from that plant were sown in a greenhouse in the following spring. Approximately 400 seedlings were selected and grown in 1 m² plots for three years. The plots were watered, weeded and fertilized alic and mowed at flowering to maintain clonal

purity. Plots were initially screened for menthone types by organoleptic methods, primarily by detecting a characteristic menthone odor. Approximately 70 plots had at least some menthone odor, but most were discarded for undesirable traits such as disease susceptibility or a "cool" menthol sensation upon organoleptic sampling. Plot number 86-183 was selected as a superior plant due to its vigorous growth habits and odor quality, having a sweet and hot odor. Subsequent chromatographic analysis of the essential oil revealed that the oil contained at least approximately 70% of the ketone menthone, which includes its isomers such as l-menthone and d-isomenthone. No disease was evident in the three years of tests with this strain.

This strain (86-183) was vegetatively propagated and grown in a 3 m² plot in two subsequent years to study oil yield, quality and disease resistance. Then it was grown on several 0.5 hectare plots by farmers in Oregon's Willamette Valley and Madras, Oreg., to study the effects of site and harvest times on oil yield and quality.

A Taxonomic Description of Strain 86-183

Strain 86-183 is a herbaceous perennial, becoming woody at the base of the stems late in the growing season. It has upright stems from the tips of horizontal rhizomes which spread vigorously in a lateral direction during the fall, winter, and early spring. Field grown plants may attain a height of 1 meter, but more commonly 6-8 dm. Herbage is glabrous except for some hairs on the veins on the lower surface of the leaves and the calyx teeth. Leaves are sessile, lanceolate, serrate (8-10 teeth on each side), and occasionally crisped. The largest cauline leaves are up to 7 cm long and 2.5 cm wide. Stems are branched in the upper portions with terminal, slender, leafless spikes of many (12-15) whorls of small flowers. Flower clusters (whorls) are subtended by a pair of lanceolate to linear bracts, the lower whorls being somewhat remote. Mature (containing mature nutlets) calyces are approximately 2.0 mm long, the upper portion dissected into 5 teeth that are less than 1 mm long with marginal and terminal trichomes (hairs). Five petals are fused into a two-lipped corolla that is pale lavender with darker splotches. The stigma is two-lobed and exserted. Fruits are small (less than 1 mm) dark brown nutlets, four per calyx. The chromosome number is $2n=48$.

The R.H.S. (Royal Horticultural Society) color of the top of the leaf is Green group 139A, while the bottom of the leaf is Green group 137C. The lavender flowers are Purple group 76C.

Strain 86-183 was very resistant to verticillium wilt and leaf rust when planted in wilt infected fields of the Willamette Valley. Only 0-3 plants in a field of 2000 plants were observed to develop these diseases in one trial. This resistance was apparently inherited from the parent (71-62) which is also highly resistant to these diseases. To demonstrate the disease resistance of strain 86-183, field trials were planted Apr. 3, 1992, in Talbot, Oreg. Two thousand plants of strain 86-183 were evaluated for mint rust (*Puccinia menthae*) and verticillium wilt (*Verticillium albo-atrum*). No incidence of rust or verticillium wilt were noted between Jun. 1, 1992, and Oct. 1, 1992.

Strain 86-183 has very aggressive stolons, growing under the soil surface, thereby providing the plant with protection from adverse weather conditions and mechanical damage.

Essential oils were obtained from the parent plant (71-62) and the strain of the present invention (86-183). The essential oil yield of strain 86-183 varies with climatic, cultural and other environmental factors. Willamette Valley trials in 1992 produced oil yields of at least 112 kg/hectare. Essential oils were obtained by steam distillation of the volatile oil of the plants using a method described in the publication *Mini Farming*, Agricultural Research Service, USDA (1963), the essential oil was then analyzed by GC/MS/DS using a Finnigan 1015C MS (mass spectrometer) interfaced by a glass-jet helium separator to a Varian 1400 GC (gas chromatograph). The glass GC column was obtained from Supelco Inc.; it was 0.75 mm ID and 60 M in length. The liquid phase was a 1 micron chemically bonded layer of Supelcowax 10 (functionally equivalent to Carbowax 20M). Samples were injected neat (without splitting). The GC injector was 220° C. and the GC column was held at 80° C. for 5 minutes, and then programmed to increase at 2° C./min to 190° C. Since some components co-eluted on the Supelcowax 10 column, the oil was also run on a non-polar (Supelco SPB-1; methyl silicone) glass column of exactly the same dimensions, and using the same temperature program as before, but the injection temperature was now 230° C.

Data was acquired and processed using a Riber 400 data system. Off-line file searching using an IBM-AT made use of a database file named KOVATS that was created under the PARADOX program from Borland International. The KOVATS database contains Kovats indices for two GC liquid phases, as well as the MW and the six most abundant ions in the mass spectrum.

Some of the components identified in the essential oil are listed in Table 1:

TABLE 1

Weight percent composition of the essential oils of <i>Mentha spicata</i> L. strains 71-62 and 86-183		
Constituent	Parent (71-62)	Strain (86-183)
*l-menthone	0.94	58.80
*d-isomenthone	0.05	17.30
*l-carvone	71.60	<0.01
*beta caryophyllene	4.27	0.04
l-menthol	0.32	0.05
*germacrene D	0.03	5.41
piperitone	<0.01	0.20

*noticeable differences in the composition of the oils from strains 71-62 and 86-183.

These results show that 86-183 differs from 71-62 in several important respects. Strain 86-183 is higher in essential oil content of l-menthone and d-isomenthone. Most notably, strain 86-183 has a much higher l-menthone content (58.8% vs. 0.94%), d-isomenthone content (17.30 vs. 0.05%), a lower l-menthol content (0.05% vs. 0.32%), and is substantially free of carvone as compared to the 71.6% carvone content of strain 71-62. The total menthone content (d-isomenthone and l-menthone) of strain 86-183 is greater than 75% (i.e., 76.1%). Strain 86-183 also has less than about 6% germacrene D, compared to less than 1% in strain 71-62.

Gas chromatographic analysis was also performed on a second sample from another plant of strain 86-183, and the results are shown in Table 2 below.

TABLE 2

Gas Chromatographic Analysis of Essential Oil From a Sample of Strain 86-183, by Weight Percent	
l-menthone	56.32
d-isomenthone	16.64
l-carvone	<0.01

TABLE 2-continued

Gas Chromatographic Analysis of Essential Oil From a Sample of Strain 86-183, by Weight Percent	
l-menthol	0.17
germacrene D	6.47
piperitone	1.15

For comparison, gas chromatographic analysis was performed on spearmint oil obtained from a *Mentha spicata* crisp Scotch plant, in this case some Farwest Scotch Spearmint Oil, 1991 crop, obtained from Aromatics, Inc., of Salem, Oregon.

TABLE 3

Gas Chromatographic Analysis, by Weight Percent of Selected Components of Spearmint Oil as Comparison	
l-menthone	0.77
d-isomenthone	0.13
l-menthol	0.01
l-carvone	64.93

The essential oil of this spearmint plant was essentially free of menthol and menthone (less than 1% of each), but was high in l-carvone concentration (more than about 60%) which gave the oil the organoleptic properties of spearmint.

As a further comparison, a gas chromatographic analysis was performed on peppermint oil obtained from a conventional *Mentha piperita* plant Murray Mitchum, in this case peppermint oil from Aromatics, Inc., of Salem, Oregon.

TABLE 4

Gas Chromatographic Analysis, by Weight Percent, of Selected Components of Peppermint Oil as Comparison	
l-menthone	22.24
d-isomenthone	3.01
l-menthol	42.48
piperitone	0.58

This peppermint oil contains characteristically high concentrations of l-menthol and l-menthone. It includes more than 40% l-menthol and more than 20% l-menthone. This level of menthone provides a characteristic peppermint taste, but the presence of l-menthol in more than trace amounts (e.g., more than 1% or 2%) provides a "cool" organoleptic sensation and produces mucosal irritation.

To demonstrate the consistently high level of carvone in spearmint oil (*Mentha spicata* native), a gas chromatographic analysis was also performed on Farwest Native Spearmint Oil from Aromatics, Inc., of Salem, Oregon.

TABLE 5

Gas Chromatographic Analysis, by Weight Percent, of Selected Components of Farwest Native Spearmint Oil *** Concentration = Relative Area % ***	
l-menthone	0.03
d-isomenthone	0.05
l-menthol	0.18
l-carvone	59.48

This spearmint oil contains characteristically low concentrations (less than 1%) of menthone and menthol, but is very high in carvone content. The oil has more than 50% l-carvone, which gives it a strong characteristic spearmint taste.

Distinguishing Characteristics of Strain 86-183

Some of the distinguishing characteristics of the essential oil of strain 86-183 are shown in the following Table 6, which compares that oil to peppermint oil and spearmint oil, and Clone 199 that was described by Tucker in *Economic Botany* 45(2):200-215 (1991).

TABLE 6

Comparison of Peppermint Oil, Spearmint Oil
and Essential Oil of Strains 86-183 and Spic-199

Oil				
Compounds	86-183	Peppermint	Spearmint	Spic-199
l-menthol	1% Max	35-45%	0%	0%
l-carvone	1% Max	0%	50%-70%	0%
menthyl acetate	1% Max	3-5%	.01-.10%	.13%
l-menthone	50-60%	18-20%	.03-1.0%	51.73%
piperitone	2% Max	10-1%	0%	10.65%

Some of the morphological characteristics that distinguish strain 86-183 from Spic 199 are set forth in Table 7:

TABLE 7

A Morphological Comparison of Spic 199 and Strain 86-183	
	Spic-199
5	Leaf blade flat
	Leaf shape lanceolate
	Leaf attachment petiole 0.5 cm long
	Leaf margin serrate
	Leaf length longest 5 cm
10	Leaf width <2 cm
	Hairiness occasional hair on veins otherwise glabrous
	Plant color dark green with purple stems and veins
15	Plant height <5 dm
	Chemotype menthone, 10% piperitone
	Strain 86-183
	may be crisped
	lanceolate
	sessile (no petiole)
	serrate
	longest 7 cm
	2.5 cm (greater than 2 cm)
	veins hairy, otherwise glabrous
	light green, no other coloration
	6-8 dm to 1 meter
	menthone, <1% piperitone

I claim:

1. A new and distinct variety of a disease-resistant mint plant, substantially as shown and described, characterized particularly as to novelty by its production of an oil with a relatively low 1-menthol content and high menthone content, when compared to the oil of its *Mentha spicata* parent, and at most only minor amounts of piperitone and 1-carvone, said oil having a peppermint-like taste and a hot odor.

* * * * *

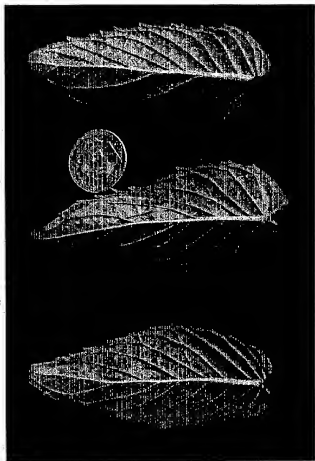


FIG. 2



FIG. 1